FINAL REPORT:

Data Investigation of Bariatric Surgery Outcome and Economic Savings

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14. ABSTRACT
This study sought to (1) define the clinical impact and economic burden of bariatric surgical procedures, and (2) estimate the cost-effectiveness and budgetary impact of obesity treatments when compared to no surgical intervention. We developed a cost-effectiveness model and a payer-based budget and fiscal impact tool to compare bariatric surgical procedures to non-operative approaches for maorbid obesity. Use of these economic models based on data from the Department of Defense (DOD) population found that all evaluated surgical interventions were cost-effective compared to non-surgical interventions. These economic assessments models can inform helath policy decisions related to obesity.

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1. INTRODUCTION

Nearly a third of all Americans are obese and obesity-related disorders like diabetes and cardiovascular disease are a leading cause of preventable death in the US. Surgical interventions like gastric bypass and adjustable banding offer the potential for significant and sustained weight loss and reversal of associated conditions, and may even reduce the risk of death related to these conditions. These interventions also come at significant financial cost, have variable success, and are still being evaluated to determine their appropriate place in emerging strategies to combat obesity from a population-health perspective. Non-surgical interventions such as behavioral changes related to diet and exercise, and medications do not result in sustained and significant weight loss when studied rigorously, but also have variable success.[1-6] They are, however, non-invasive and are viewed by many as being less costly (at least in the short run) than surgical approaches.

While there has been considerable research focused on the costs and effectiveness of bariatric surgery, there has been little, systematically gathered evidence on the non-surgical care and healthcare expenditures for similarly burdened patients. This study sought to carefully define the clinical impact and economic burden of both surgical and non-surgical interventions to help guide the Department of Defense (DOD) decision making for patients with obesity and related disorders. In addition, this study aimed to understand the cost-effectiveness of obesity treatments, a critical element given the cost of treatment procedures, their potential for saving future costs related to comorbid health conditions and worker productivity, and the growing numbers of patients who might be considered “eligible” for surgery.

This study tested the hypotheses that: (a) surgical interventions for extreme obesity are more cost-effective than non-operative approaches; (b) in certain subgroups of patients and procedures, operative approaches represent dominant technology compared to non-operative approaches; and (3) a healthcare strategy that directs more patients with extreme obesity to bariatric surgery will decrease healthcare expenditures by a single-payer over 5, 10, and 20-year timelines with increasing savings identified over longer timelines. This study has produced a comprehensive assessment of the burden and costs of operative and non-operative obesity care across all regions in the U.S. where the DOD authorizes care. To test these hypotheses, we created a collaborative group of leading experts in bariatric surgery, obesity care, epidemiology, health services research, modeling, and health economics, as well as other key stakeholders. We gathered all available, relevant data sources and developed new data sources as needed. We created an appropriately complex 2 –stage model to evaluate lifetime costs, quality of life, and outcomes, and used advanced simulation techniques to evaluate variability in the data and among different populations.

These economic assessment tools will allow health policy experts, purchasers and payers of healthcare, clinicians, and patients to better understand the utility and cost-effectiveness of available treatment strategies. These economic considerations will be increasingly important as payers try to address the companion crises of spiraling health care costs and the loss of productivity related to obesity.

2. BODY

2.1 Background

Morbid obesity is an epidemic in the United States (U.S.) affecting over 15 million people. The prevalence of obesity has doubled since 1980 and is now seen by the Centers for Disease Control (CDC) as one of the top threats to the health of the nation.[7] There is strong evidence that obesity is associated with Type 2 diabetes,[8-14] hypertension,[8, 15-22] sleep apnea,[23-25] dyslipidemia,[8, 15, 26-27] heart disease,[18-21, 28-31] asthma,[32-33] gastroesophageal reflux, [34-38] fatty liver disease,[39-42] and back problems,[43-44] and that such conditions are improved or resolve following weight loss. Further, morbid obesity is associated with a substantially increased risk of death due to chronic health conditions. [45-46] A landmark prospective study of more than one million U.S. adults demonstrated that the relative risk of death from all causes was 1.5 to 2.8 times greater among morbidly obese adults compared with normal weight adults.[47] In studies comparing life expectancy between normal weight and obese individuals, a 12 year loss of life is predicted for a 25 year old who is morbidly obese and a 7 to 11 year loss of life for a 40 year old compared to their normal weight counterparts.[46] It has also been reported that among the 111,909 excess deaths associated with obesity in 2000, most (82,066 deaths) occurred in individuals with a BMI of 35 or greater.[45]

In addition to the increased health risks associated with obesity are the associated increases in costs.[48-54] The disease has been estimated to account for 9.1% of annual U.S. medical expenditures or as much as $92 billion,[48] therefore making obesity outrank both smoking and drinking in its effects on health care costs.[52] According to the National Institutes of Health (NIH) and the Surgeon General, approximately $123 billion of all U.S. health care related costs in 2003 were spent on obesity or obesity-related complications.[55] The Congressional Budget Office reports that medical funding for Department of Defense (DOD) will grow to $59.3 billion in 2025.[56]

Studies on private health plan enrollees[37, 50] have demonstrated that the high cost of obesity is associated with 24% higher outpatient visits, 74% higher annual hospital days, 78% greater pharmacy visits, and 85% greater laboratory visits[50] relative to normal weight cohorts. In addition, obese patients had greater use of cardiovascular, asthma, ulcer, diabetes, thyroid, and analgesic medications, compared with normal weight patients.[37] Significant expenditure differences exist, however, across various levels of obesity.[34] It has been reported that a BMI of 30 to 35, 35 to 40, and over 40 result in health care cost increases of 25%, 50% and 100%, respectively.

Although the costs of morbid obesity are well established, it remains unclear whether bariatric surgery substantially reduces these costs because there have been few economic evaluations of bariatric procedures. The sparse literature on cost-savings following bariatric surgery is typically based on surgeries performed at a single site, most frequently assesses savings in health systems outside the US using limited before-after comparisons, and provides conflicting evidence as to whether the costs of bariatric surgery are eventually offset by subsequent reductions in medical care expenditures.

While there is extensive literature on the outcomes of obesity, outcomes analysis in bariatric surgery suffers from a lack of wide population-based evaluations. In published reports of surgical care, selection bias, publication bias, and a predominance of case series preclude meaningful assessments of outcome. For example, one of the most widely quoted papers about the outcomes of bariatric surgical interventions is a meta-analysis sponsored by a surgical device manufacturer and published in the Journal of the American Medical Association (JAMA).[9] The article summarized the findings of 131 published reports, of which more than 75% were case series from individual centers, the inclusion of all consecutive patients was not a requirement, follow-up ranged from unrecorded to 50-80% (average was less than 70%), and no standard endpoints were used.

While a lack of high quality information on cost and outcome may limit the accuracy of cost-effectiveness evaluations, better information will emerge over time and can be incorporated into models. Taking a health economics approach to obesity and obesity treatments can also direct clinical research efforts pertinent to improving obesity healthcare over the long-term. This approach will also allow for new interventions to be evaluated once information on cost and outcomes become available.

Proper adaptation of a cost-effectiveness approach to obesity interventions will help avoid: (1) not adopting a technology that has great health value for expenditure; (2) adopting a treatment that increases costs but has no benefit, or for which harms that exceed benefit; and (3) adopting a treatment with poor value for expenditure, i.e.,, for which greater benefit could be gained elsewhere for the same investment.

In this study, we proposed a comprehensive assessment of the burden and costs of operative and non-operative obesity care across all regions in the U.S. where the Department of Defense (DOD) authorizes care. The global aim is to use this data and modeling techniques to create a portfolio of research on the economics of obesity and its treatments. Specifically, we proposed to develop an economic assessment tool that will allow health policy experts, purchasers and payers of healthcare, clinical triallilists, clinicians, and patients better understand and project the utility and cost-effectiveness of available treatment strategies.

Developing a payer perspective, cost-effectiveness assessments for healthcare policy decision-making related to non-operative and operative approaches to obesity will provide highly detailed evaluations of obesity treatments across different patient populations. These assessments should include non-operative and operative approaches to obesity (i.e., is bariatric surgical care cost-saving compared to non-operative approaches for the covered population). They should also include a payer-based budget and fiscal impact tool to assess "return on investment" for obesity-related operative interventions compared to non-operative interventions based on patient characteristics (i.e., is bariatric surgery for a 40 year old man with a body mass index (BMI) of 40 more cost effective in a 3 year time line than non-operative care). any payers currently do not provide coverage or inadequate reimbursement for bariatric operations presumably because of the high upfront cost and low perceived long-term benefit and economic return. Some payers, however, do cover less effective weight loss treatments and long-term healthcare expenses associated with obesity. For example, the direct medical costs associated with obesity alone were estimated at $56 billion in 2002, but the costs associated with type 2 diabetes mellitus in the

same year totaled $132 billion.[57] The cost-effectiveness and budget impact analyses developed through this project will provide a unique resource to the community to allow payers to predict how a change in use of bariatric operation (such as to less diseased, but high BMI patients) will impact both short and long-term spending for obesity. This approach may help direct healthcare payers to increase the use of bariatric operations as a treatment for obesity in populations most likely to benefit.

2.2 Research Activities

AFDW collaboration: An on-site kickoff meeting was conducted on November 21, 2008 with University of Washington (UW) project staff and four United States Air Force Surgeon General Research and Development Division (AF/SGRS) affiliates. The meeting served as a site visit and included presentations and discussion of the various datasets examined for their potential to inform our simulation model. A detailed description of each dataset and our evaluation criteria were also included. Meeting minutes were reported to AF/SGRS.

An on-site peer review meeting was hosted on September 11th, 2009 with UW project staff, AF/SGRS representatives and Subject Matter Expert, Major Peterson. The meeting was focused on providing a review of study progress to date as well as a peer review of the micro-simulation model. The presentations provided a review of completed milestones including the literature review, dataset selection and integration, and development of the micro-simulation model, as well as challenges and resolutions encountered throughout the project.

A narrative report detailing the micro-simulation model and associated analyses in conjunction with meeting materials provided during the September 11th meeting made up the year one summary report and was submitted to AF/SGRS as part of the September 2009 monthly progress report. We further expand on the final micro-simulation model methodology and associated analyses in the Detailed Technical Report section below.

An on-site final review meeting was conducted on September 17th, 2010 with UW project staff and AF/SGRS representatives. The meeting was focused on providing a detailed presentation of the Cost Effectiveness and Budget Impact Models as well as a high-level summary of research accomplishments in preparation for the final report. TRICARE data were run through both models to demonstrate model capability and foster a discussion on implications for DOD policy. A copy of the presentation materials has been included in the compact disc accompanying this report.

Research Project Organization and Kick-Off:
An early objective was to recruit and fill project staff positions for the following roles: biostatistician, data analyst, health services/health economics post-doctoral fellow. Each of these positions was filled; Dr. Rafael Alfonso joined the research team as a health economist post-doctoral fellow, Kara MacLeod joined as a health services data analyst and health service researcher, and Dr. Bruce Wang accepted the biostatistician position. Resumes and/or biosketches for Dr. Alfonso, Ms MacLeod and Dr. Wang were provided to AF/SGRS and posted as addendum to the monthly technical progress report.

An Institutional Review Board (IRB) application was submitted to the UW Human Subjects Division at the initiation of the project. The UW submission was approved on December 29th, 2008. SGRC approval was received on March 6th, 2009. Copies of the UW and SGRC approvals as well as subsequent approved modifications including modifications to add additional datasets were submitted to Ms Jessica Candia at SGRC.

Administrative Dataset Evaluation and Purchase: This study aims to quantify the burden of surgical and non-surgical obesity care costs and outcomes across various regions in the U.S. and

develop an economic assessment and policy-planning tool. To achieve these ends, we selected databases based on their unique strengths in populations and data available, and tried to find sources complementary to one another or addressing areas where other databases are lacking. When observed together, these datasets provide a view of demographic characteristics, inpatient and outpatient utilization, emergency room visits, overnight hospitalizations, out of plan referrals and claims, laboratory tests, laboratory test results, medications ordered and pharmacy prescriptions filled at health plan pharmacies. No single database provided all of these components of care but taken together they represent the global care received by patients in regions with obesity and obesity surgery. Data Use Agreements were acquired for the following data sources: Air Force TRICARE, Group Health Cooperative (GHC), Medical Expenditure Panel Survey (MEPS), Medicare, Medstat MarketScan®, National Center for Health Statistics (NCHS), and the Surgical Care and Outcomes Assessment Program (SCOAP). A detailed description of each data source including population and design, primary data elements and uses and limitations is presented in Appendix 2.

In addition, we received institutional review board (IRB) approval to conduct an Adjustable Gastric Band (AGB) primary data collection study to create a novel dataset evaluating post-operative healthcare utilization and quality of life in patients undergoing AGB. A copy of the IRB approval was provided to Ms Jessica Candia.

<u>Literature Review</u>: Although care and costs of surgical and non-surgical obesity care were predominantly extracted from secondary administrative data sources, current literature was used to inform certain gaps of missing information important to the economic assessment and policy planning tools. For example, we used available literature for assessing the natural progression of obesity over a lifetime or natural weight loss, which was difficult to identify through administrative coding of patients (ICD-9 or CPT).

Over the course of the first nine months of the project, the study investigative group identified areas of potential gaps in data obtained from secondary administrative data sources. These identified areas become literature search topics. National Library of Medicine's Medline/PubMed database was then searched for relevant clinical and research reports. Over 9,500 articles were mined from PubMed, reviewed for relevance, and narrowed to roughly 125 based on specific criteria. Selected articles were reviewed, synthesized and tabulated into an easily searchable report for future inclusion into economic assessment and policy planning tools as necessary. This literature review report has been included on the compact disk containing the Cost-Effectiveness Assessment and Budget Impact Models delivered to the DOD.

<u>Economic Evaluation Tools:</u> We developed two economic evaluation tools for comparing operative to non-operative approaches to treating obesity.

The first—a cost-effectiveness model —addresses the question: is bariatric surgical care cost-effective compared to non-operative approaches for obese patients?

The second—a payer-based budget and fiscal impact tool—assesses "monetary return on investment" for obesity-related operative interventions compared to non-operative interventions,

addressing the question: at the payer level, what financial impact would coverage for bariatric surgery have on total plan costs?

This information will be useful to healthcare insurance payers seeking the most effective and cost-effective treatments for obese patients. Many payers currently do not provide coverage or inadequate reimbursement for bariatric operations presumably because of the high upfront cost and low perceived long-term benefit and economic return. Some payers do, however, cover less effective weight loss treatments and long-term healthcare expenses associated with obesity. For example, the direct medical costs associated with obesity alone were estimated at $56 billion in 2002, but the costs associated with type 2 diabetes mellitus in the same year totaled $132 billion.[57]

These cost-effectiveness and budget impact analyses will provide a useful resource to the research and policy community to allow payers to assess how a change in use of bariatric procedures (such as to less diseased, but high BMI patients) will impact both short and long-term spending for obesity. We anticipate these outcomes will direct healthcare payers in widening the use of bariatric operations as a treatment for obesity, thus improving the obesity treatment options available for clinical management of obese patients. Lastly, these two tools meet the specific aims set forth in the initial proposal:

> *Specific Aim 1*: Quantify the burden of non-surgical, obesity care costs/expenses and outcomes across various regions in the U.S. where DOD authorizes care
>
> *Specific Aim 2*: Quantify the burden of surgical costs/expenses and outcomes across various regions in the U.S. where DOD authorizes care
>
> *Specific Aim 3a:* Develop preliminary payer perspective, cost-effectiveness assessments for healthcare policy decision-making related to non-operative and operative approaches to obesity (i.e., is bariatric surgical care cost-saving compared to non-operative approaches for the covered population).
>
> *Specific Aim 3b*: An emerging field in economics—value-of-information (VOI) analysis—applies methods from economic theory and decision analysis to evaluate the value of research to society and individuals. Specifically, VOI can be used to determine the expected humanistic and economic value of the information gained from a particular research study, stated in years of life gained (YLG), quality-adjusted life years (QALYs), and monetary terms. We propose to make VOI computations for surgical and non-surgical obesity interventions using the economic model developed in Aim #3a in order to inform the design of future clinical research studies.
>
> *Specific Aim 4*: Develop a payer-based budgetary tool to assess "return on investment" for obesity-related operative interventions compared to non-operative interventions based on patient characteristics (i.e., is bariatric surgery for a 40 year old man with diabetes and a BMI of 40 more cost effective in a 3 year time line than non-operative care).

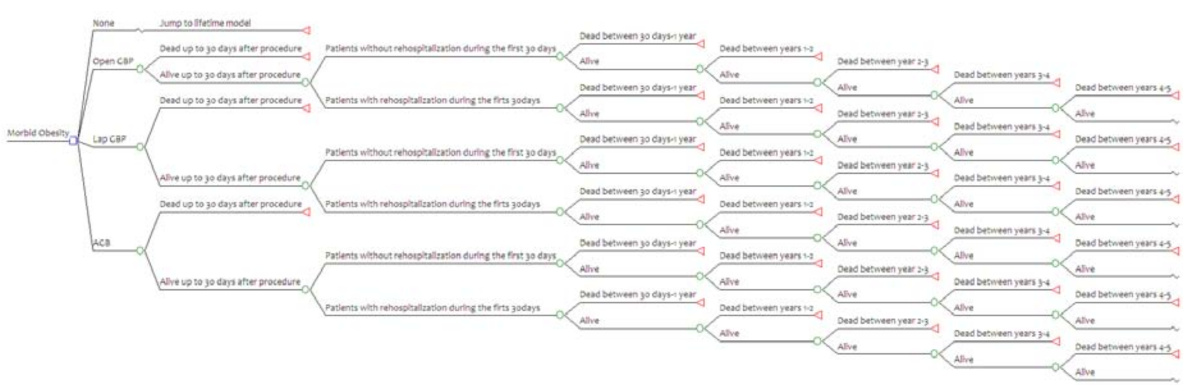
2.3 Detailed Technical Report

2.3.1 Cost-Effectiveness Assessments

Overview: The core analytic engine is a cost-effectiveness simulation model (CEM) in which we estimate the lifetime costs and outcomes associated with various bariatric procedures for individuals with specific baseline characteristics, including BMI. The model is divided into 2 parts: 1) a decision-analytic model to cover the initial post-operative period and the first 5 years post-surgery and 2) an empirical "natural history" model starting in the 6th year post-surgery and comprised of a number of interconnected regression equations to forecast expected lifetime changes in BMI, life expectancy, costs, and quality of life. The reason for having a two-part model is because we have clinically rich data for the first 5 years, which allows us to model more complex clinical scenarios. However, data availability after 5 years is limited, so the forecasting model gives us the flexibility to estimate long-term outcomes based on fewer clinical inputs. We provide the user with our "best" estimates for the parameters in the model, but a sophisticated user can change most everything from data source to regression type to discount rate. The model is programmed in Microsoft Excel with substantial parts of the analysis done in SAS 9.2 and Stata 11.0.

Part 1 – Decision Tree

Figure 1: Overview of decision tree for first five years



Source: Bariatric Outcomes and Obesity Modeling (BOOM) Research

A decision-analytic model was developed to assess the short-term impact of the surgical procedures, considering the benefits, complications, and costs within the first 5 years (Figure 1). Each surgical procedure is simulated to estimate the initial clinical outcomes, costs, and utilities from the procedure to a weight stabilization period after 5 years. There are 4 initial decision branches: 1) No Surgical Intervention, 2) Open Roux en Y Gastric Bypass (ORYGB), 3) Laparoscopic Roux en Y Gastric Bypass (LRYGB), and 4) Adjustable Gastric Banding (AGB). Each of these branches—except for the "No Surgical Intervention", which utilized the natural history model—has subsequent clinical pathways during the first five years representing the probability of the most relevant events associated with the surgical procedures at different time points.

The first set of outcomes in each branch covers the first 30 days and has two states: 1) Death within the first 30 days after the procedure or 2) Alive up to 30 days after the procedure. This is one of the most relevant outcomes since the mortality associated with bariatric procedure is highest during this first period. Then, for patients who survive the first 30 days after the procedure, we identified two further subgroups based on early re-hospitalization or no re-hospitalization within the first 30 days after the procedure. We based this decision on the published data from Encinosa et al.[58] and our own preliminary analyses that showed patients with extended length of stay during the first 30 days after the procedure have a higher probability of complications, health resource use, costs, and mortality.

The subsequent branches in the first part of the model are populated with data on treatment effectiveness, complication rates, mortality, costs, and utilities summarized each year after the procedure until year 5, at the end of which survivors are entered into the second part of the model to continue the simulation. The probability of death at each period is derived from data provided from our data sources including SCOAP, GHC patient-level database, Tri-care, Medstat and Medicare, and is validated by comparison with published literature.

After testing several alternative specifications for cost projections, we chose to model annual costs as a gamma distribution with a log-link function. We believe our current method has many advantages including: 1) exhibiting skewness towards low values; 2) having a lower bound of zero; and 3) being consistent with the methodology of competing studies. The decision-analytic model requires costs for those who are alive and costs for those who die. For the former, we use data from GHC, and, for the latter, we use Medicare data. We adjust the cost data for inflation in different time periods using the overall Consumer Price Index (CPI) obtained from the Bureau of Labor Statistics.

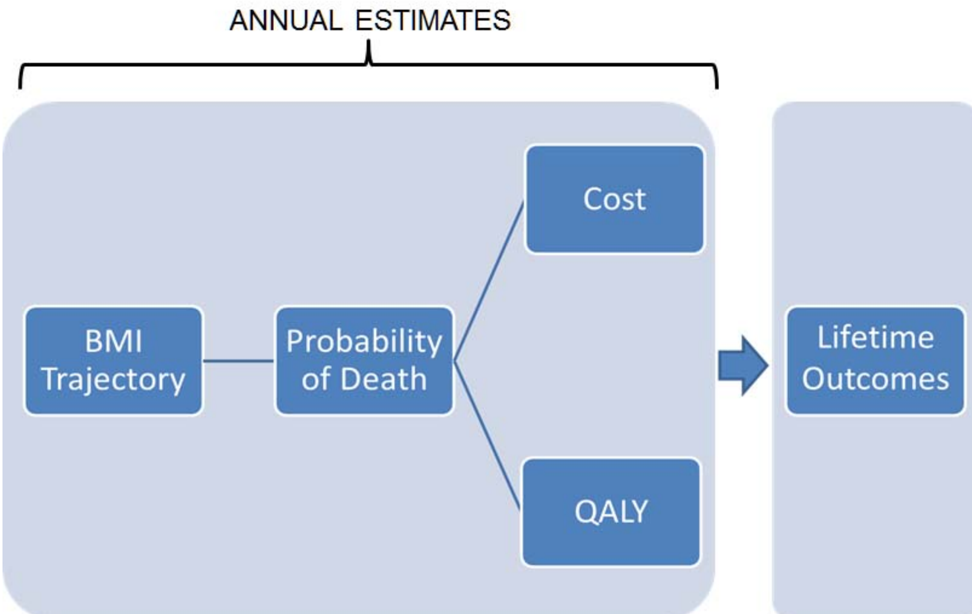
We use total annual expenditures as our cost variable and regress it on procedure type (open bypass, lap bypass, and band), cohort (death within 30 days, alive with rehospitalization or prolonged length of stay [PLOS], alive), BMI, Age, and Sex. We do this separately for each of the periods of the first part of the model—0-30 days, 31 days – 1 year, Year 2, Year 3, Year 4, and Year 5. Medicare data do not have BMI, so we drop that term from the regressions for estimating the costs in the period in which individuals die.

Utilities and changes in BMI associated with each procedure have been drawn from published sources— specifically from the report published by Picot et al.[59] and individual clinical trials assessing the quality of life and changes in utility following the first 30 days after the procedure. Utilities for subsequent years after the procedure are modeled using MEPS, the only dataset for which we have that measure. Specifically, we transform the SF-12 Health Survey value into EQ5-D Health Survey according to work from a prior study.[60] Although MEPS has repeated measures of BMI and the SF-12 for individuals, we estimate our equations on the cross-section because the measurement dates for each variable in the time-series are different. Our linear model regresses utilities on BMI, Age, and Sex. Given the coefficients from the regression and our knowledge of the values for the covariates, we can generate a predicted utility for each procedure and cohort in each period.

The results indicate that higher BMI and Age are associated with lower utility. Also, there is a disutility to being Female. Although our mapping allows for negative utilities, death has a utility value of 0. Using results from literature, we provide an adjustment for utilities in the first 30 days post-surgery for those who were rehospitalized or had PLOS.

Part 2 – Lifetime Natural History Model

Figure 2: Overview of lifetime natural history model



Source: BOOM Research

As previously described, patients who do not have a bariatric procedure follow a natural history pathway; hence, by definition, they enter the lifetime trajectory model immediately, i.e., five years earlier than a similar surgical procedure patient. For everyone else, they are transitioned from the decision-tree model after 5 years. For example, a 40-year-old surgery patient will remain subject to the surgery-specific decision-tree until age 45 and enter the lifetime trajectory model after that to produce a trajectory of BMI up to death or age 100 (when death is assumed). The major output of this model is to provide a trajectory of annual estimates of BMI conditioned on survival. Given the BMI values, we can then predict outcomes at each period to complete the cost-effectiveness analysis. Figure 2 shows the flow from annual estimates to lifetime outcomes for an individual entering the natural history model.

We have individual data on BMI at different time points for over 60,000 individuals who have reached a BMI of 35 kg/m^2 or greater at any given time through the GHC dataset: some of these individuals have been followed in a breast cancer screening program for over 20 years, but most data are from the last 5 years after the implementation of GHC's electronic medical record system. We use this information to inform our model and develop a BMI-driven natural history model that projects the trajectory of mortality, costs, and utilities associated with the changes in BMI at any given time for the specific characteristics of the reference patient. In their

publication, Heo et al.[61] recommend using hierarchical linear models (HLMs) as the best alternative for developing trajectories when data are available on multiple individuals measured at multiple time points that may vary in number or inter-measurement interval, which is the case of our dataset from GHC. According to the authors, estimation through HLM has an advantage over the ordinary least squares (OLS) approach, because the latter does not model the between-individual variations of growth trajectories. They modeled BMI variation in growth curves from four longitudinal databases as a function of subjects' baseline characteristics. They compared five different models using different random coefficients but in the same form.

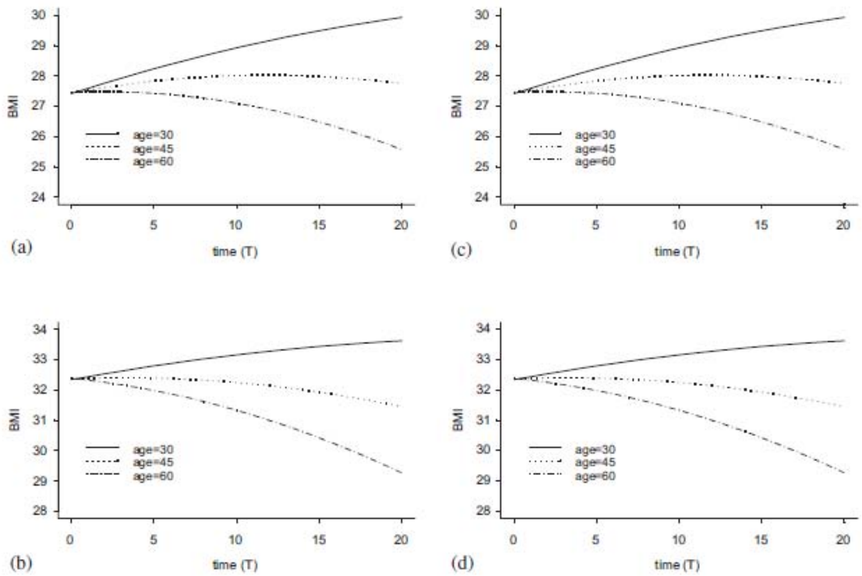
The best model they found to predict BMI (Y) at time t, (that is, t from baseline) was:

$$\boxed{Y(t) = 0.266 + 0.0014Age - 0.036Sex + 0.985BMI + (0.759 - 0.0051Age - 0.026Sex - 0.016BMI)t + (-0{:}0037 - 0.00011Age + 0.00033Sex + 0.00016BMI)t^2}$$

For this model, all the estimated coefficients are significant ($p<0.05$) with the exception of the estimated intercept (−0.0037) for the quadratic time term. These results indicate that the BMI natural history trajectory depends on Age, Sex, and initial baseline BMI. Their results showed that BMI tends to increase over time for younger people with relatively moderate obesity but decrease for older people regardless of degree of obesity. The gradients of such changes are inversely related to the baseline BMI, but do not substantially depend on gender, although women tend to gain more and lose less weight than do men. Figure 3 shows examples of the HLM BMI trajectory for individuals of different ages, genders, and initial BMI values.

If we add the HLM BMI trajectory to the Picot et al.[59] BMI estimates from the decision tree, we can predict the lifetime BMI trajectory for a bariatric surgery patient (see Figure 4). The example shows the BMI paths for a Female, BMI=42, Age = 45 given surgical and non-surgical choices. In each case, there is eventually a decline in BMI due to an increase in age as forecasted by the HLM model. For the surgical options, the U-shaped path in the first 5 years reflects the weight regain after surgery.

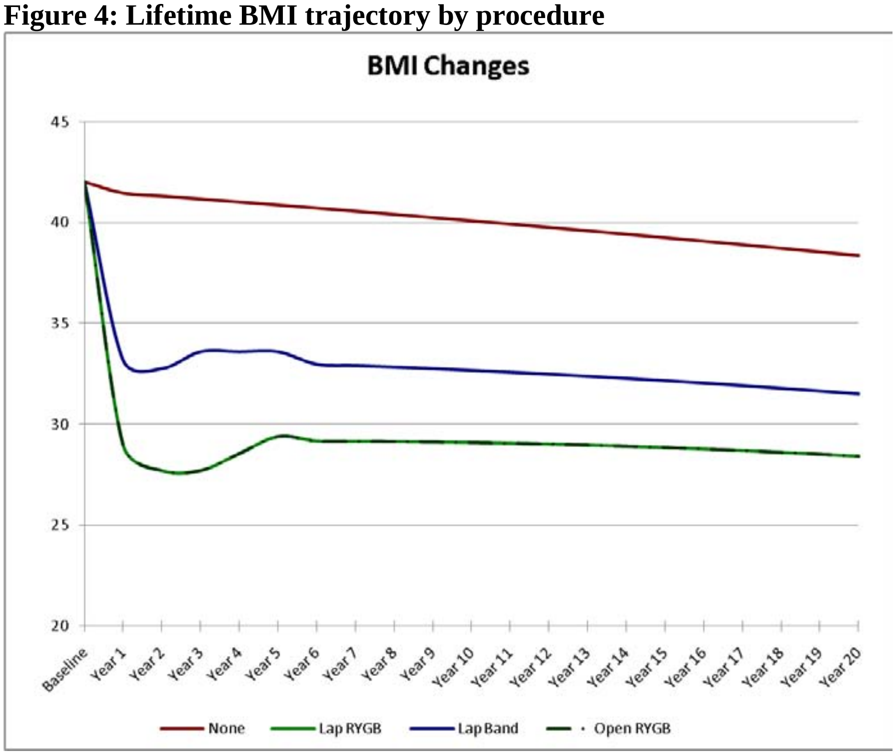
Figure 3: BMI trajectories using HLM approach[61]



(a) for men with baseline BMI 27.5; (b) for men with baseline BMI 32.5; (c) for women with baseline BMI 27.5; (d) for women with baseline 32.5.

Source: Heo et al.[61]

Figure 4: Lifetime BMI trajectory by procedure



Source: BOOM Research

Survival probabilities were obtained from static life tables stratified by BMI and Sex. We constructed these life tables by estimating the 5-year probability of death from a logistic regression model. We estimated 5-year death as a function of Sex, BMI, squared BMI, Age, squared Age as well as interactions for Sex/Age, Sex/BMI and BMI/Age. Data were from the NCHS National Health Interview Survey (NHIS) between the 1997 and 2001. Respondent were linked to the National Death Index (NDI) allowing for mortality follow-up through December 31, 2006. Analogous to Schauer et al.,[62] our modeling focused on respondents with a BMI of 25 and above. The regression model excluded respondents below this threshold. The logistic model uses 5-year death as the dependent outcome because of the limited very low incidence of death annually. Predicted 5-year death probabilities are used to calculate equivalent one-year probabilities using appropriate translations between instantaneous rates and probabilities. Consistent with previous literature, our results show that death probabilities are higher among males and increase with increasing age and BMI. Also, the increase in mortality risk due to obesity decreases as individuals increase in age. These predicted death probabilities were used to generate life expectancy given sex, age, and BMI using standard life table methods (Table 1).

Given the predicted BMI and survival probability in each period, we can estimate utilities in the same manner as in the decision tree. Specifically for those who survive, we projected utility—a value between 0 and 1—as a linear function of BMI, Age, and Sex. For costs, we used the same dataset (i.e. MEPS), and employed the same methodology except our dependent variable was total annual expenditure.

Part 3 – Results

From our lifetime natural history model, we can make predictions on the outcomes of individuals if they were to lose different amounts of weight. Table 1 shows the different lifetime costs, lifetime QALYs, and life expectancy of a 45-year old female with different starting values of BMI. If she starts at BMI=25, her lifetime expected cost and QALYs are $155,443 and 21.26, respectively, at 3% discount rates. We forecast her to live until age 83, which is 38 additional years of life (undiscounted). As BMI increases, lifetime cost increases while lifetime QALYs and life expectancy decrease.

Table 1: Predicted lifetime outcomes for a 45-year old female

BMI	Cost	QALY	Expected Age of Death
25	$ 155,443	21.26	83
35	$ 168,965	20.04	80
45	$ 182,149	18.81	77

Source: BOOM Research

A 45 year-old female subject with a BMI of 40 kg/m^2 was simulated in the model and followed until death, comparing the three different surgical interventions to the non-surgical approach. The results are shown in Table 2.

Table 2: Lifetime outcomes of surgical and non-surgical options

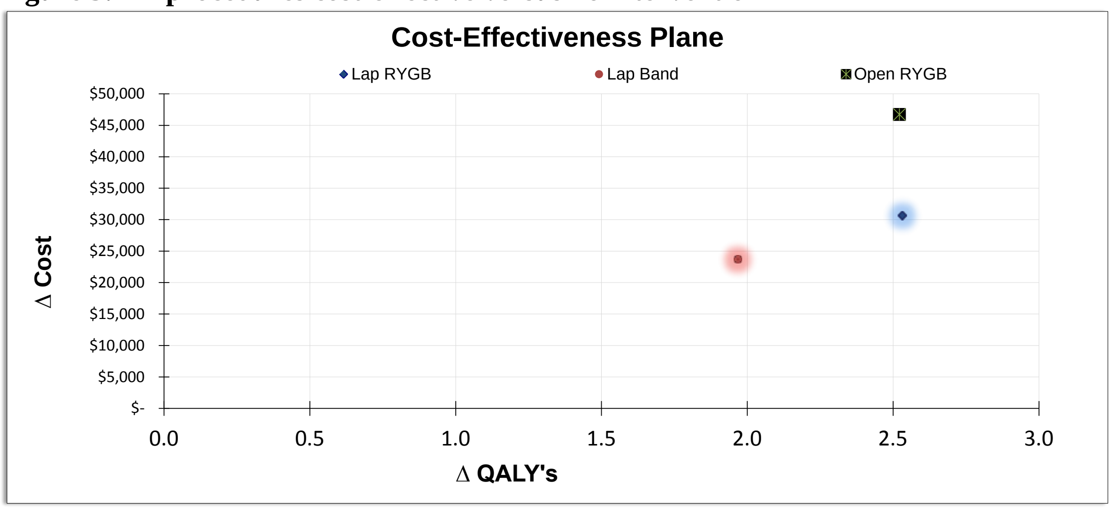
Lifetime Outcomes				
Intervention	**None**	**Lap RYGB**	**Lap Band**	**Open RYGB**
Costs	$ 382,014	$ 401,816	$ 400,637	$ 419,186
QALY	37.31	41.33	40.37	41.32
Expected Age of Death	78	83	82	83
ICER		$ 4,927	$ 6,083	$ 9,273
Net Benefit		$ 382,137	$ 287,514	$ 363,698

Source: BOOM Research

Compared to a non-surgical approach, a 45 year-old female with a BMI of 40 kg/m^2, would increase her life expectancy by 4 to5 years by having an AGB or ORYGB procedure, respectively. The additional gains in QALYs with the surgical interventions would come at an additional cost of between $5,000 to $9,000 per QALY gained depending on the intervention selected.

Assuming a (conservative) cost-effectiveness threshold of $50,000 dollars per QALY gained in the US, all of the surgical interventions would be judged as cost-effective when compared to non-surgical approaches (Figure 5).

Figure 5: All procedures cost-effective versus no intervention



Source: BOOM Research

<u>Part 4) Sensitivity Analyses, Validation, and Value of Information</u>

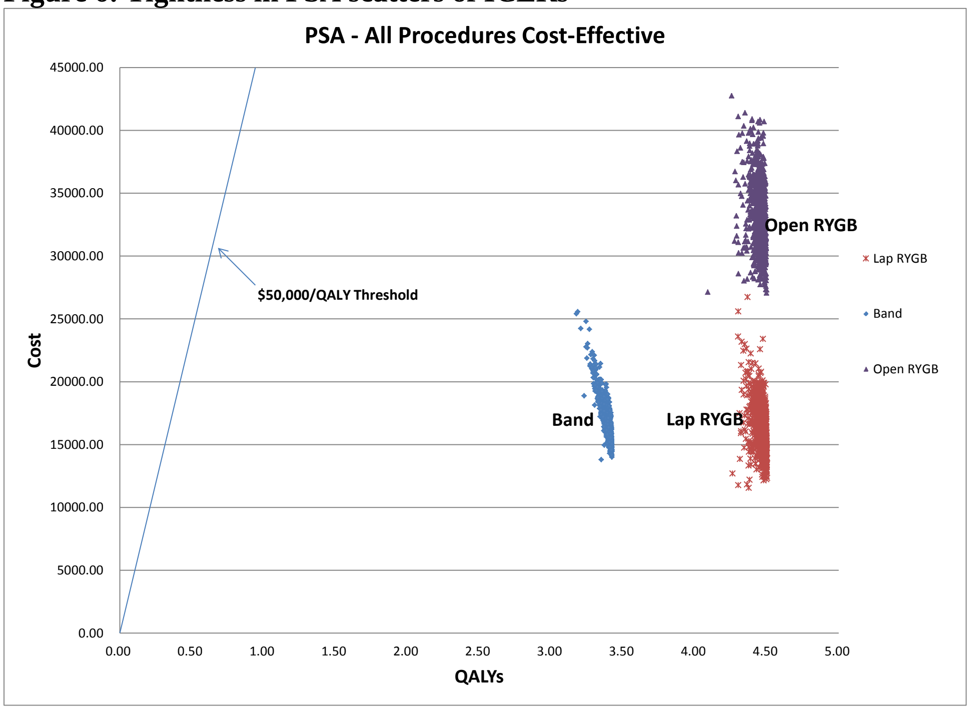
In this section, we report the results of a validation procedure, structural, and parameter sensitivity analyses, and the value-of-information (VOI) analysis. We start by describing the probabilistic sensitivity analysis (PSA) using a distribution of parameters rather than the static values used to generate the current model findings. Then, we report the findings from a replication exercise, the purpose of which was to internally validate the cost-effectiveness model. We then report the outcomes of our efforts to investigate the robustness of our findings by employing alternative methodologies and data sources. Finally, we describe the VOI computation.

i) Probabilistic Sensitivity Analysis

We made random draws from beta distributions for the mortality and complication rates of each procedure in the decision tree. The parameters for the beta distribution come from CMS data. Other inputs to the model, such as costs and QALYs, are inferred from regressions and thus do not have PSA distributions.

The results of the PSA simulation (1000 trials) on excess cost and QALY relative to no intervention are shown in Figure 6. Most of the uncertainty for each procedure is in terms of costs: there is little variation in QALYs. Despite slight differences in the outcomes from each simulation, every trial is cost-effective at a conservative willingness-to-pay threshold of $50,000/QALY. In fact, even if the threshold is lowered to $10,000/QALY gained the procedures still would be considered cost-effective relative to no intervention.

Figure 6: Tightness in PSA scatters of ICERs



Source: BOOM Research

ii) Replication of Model in Alternative Software Program

To validate the complex calculations in the Excel-base model we replicated the programming in a different programming language, SAS 9.2. This serves two primary purposes: 1) it allows us to confirm that each of the sub-models (survival probabilities, BMI trajectory, etc.) are programmed correctly; and 2) SAS is a powerful program that is more efficient at handling large datasets, which allows us to perform simulations on millions of hypothetical individuals.

Using the SAS version of the model, we then performed a simple simulation of the entire US population to illustrate the generalizability of our model. We used the sample from the NCHS National Health and Nutrition Examination Survey (NHANES) and applied statistical weights to

simulate the current US population. Table 3 shows the average outcomes per capita given the current population and under different scenarios of weight loss for the obese population.

The simulation shows that the average lifetime cost per capita is $135,246 for the current population. If we reduce the BMI of the obese population by 10%, this reduces the average lifetime cost per capita to $134,313. Note that this reduction is on average across all individuals including those in the normal and overweight BMI categories.

Table 3: Simulations for the entire U.S. adult population

	Cost	QALY	Life-Years
Current Population	$ 135,246	20.80	36.10
10% BMI Reduction	$ 134,313	20.90	36.30
20% BMI Reduction	$ 133,368	20.99	36.50
30% BMI Reduction	$ 132,412	21.08	36.70
40% BMI Reduction	$ 131,444	21.18	36.90
50% BMI Reduction	$ 131,400	21.21	37.10
Reduction only in those above 30 BMI			

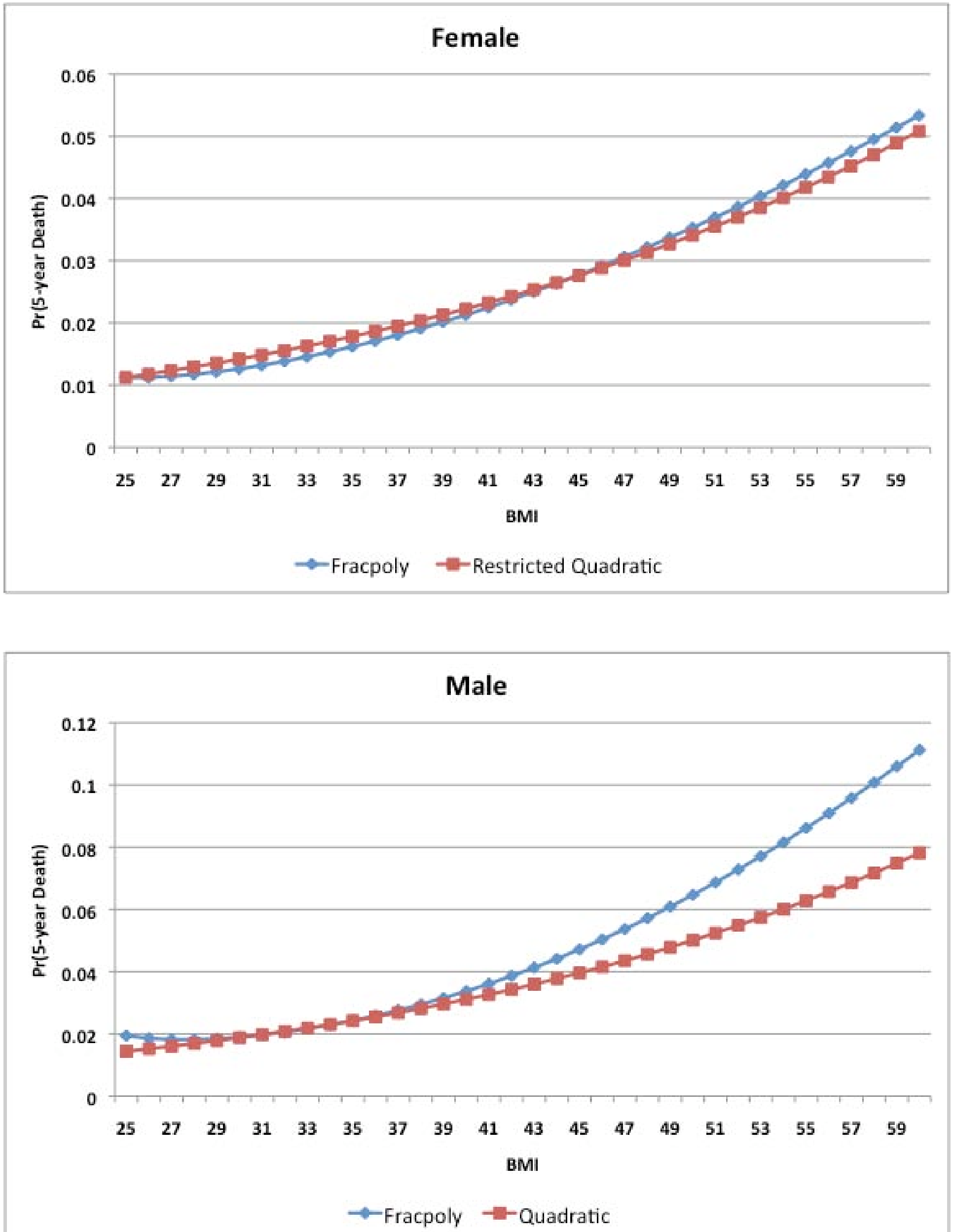
Source: BOOM Research

iii) Same Results Using Alternative Methodology

There exist a number of different methodologies for estimating the BMI-mortality relationship. As explained in the methodology section, we treat BMI as a continuous variable to capture the non-linear relationship with mortality by imposing a quadratic functional form. In this section, we show that using an alternative approach for modeling these survival probabilities does not affect our end result.

Specifically, we estimate mortality using the Multivariable Fractional Polynomials (MFP) method.[63] The advantage of the MFP method is the ability to endogenously select the best fitting adjustment variables in the logistic regression model. In other words, the data determine the functional form for BMI. Figure X provides a comparison of the MFP model and the subsampled quadratic model for respondents with BMI > 25 who are employed in this study. For females, the model fit is nearly identical. For males, there exist divergences at the right tail of the BMI distribution. Specifically, the estimated probability of 5-year death at high BMI levels is higher in the MFP model. However, the curve for the quadratic model is within the 95% confidence interval of the MFP model. For a 45-year old male with BMI = 40, the expected years of life remaining are26.36 in the MFP model compared to 28.86 in the subsampled quadratic model. When using this alternative approach in our model, the end results is still that bariatric surgery is cost-effective relative to the alternative of no surgery.

Figure 7. Comparison of BMI-mortality curve for a 45 year old, using multivariable fractional polynomials and the quadratic model for BMI > 25.



Source: BOOM Research

iv) Value of Information (VOI)

When conducting health economic assessments based on imperfect information (e.g. evidence on expected weight loss or changes in utility may be lacking or highly variable), it is often useful to assess the value of collecting "more perfect" information. Value of Information (VOI) analyses can help direct future studies and inform the prioritization processes of research funding agencies

and investigators. For example, if the impact of information uncertainty on modeled outcomes is trivial, then acquiring perfect information may not be worth the investment in future studies.

To evaluate the potential utility of VOI in informing the decision to fund a clinical trial or to gather additional data to improve the estimates used in the cost-effectiveness analysis, it is necessary to gather information on costs and benefits (survival, health state preferences) of the interventions that are available at the time. Using these data and the model developed in Aim 3a, we can compute parameters required for calculating the VOI: the incremental net benefit, expected value of perfect and sample information, and the expected net benefits of sampling.

The initial step for a VOI analysis is determining the net benefit of the new treatment versus an alternative, and the uncertainty in that value. NB is calculated as:

$$NB = \lambda\left(QALY_{new} - QALY_{alt}\right) - \left(C_{new} - C_{alt}\right)$$

Where λ = the societal willingness to pay for a quality adjusted life year (QALY). Typical thresholds for societal value of a QALY are $50,000 and $100,000. To compute the net benefit, one estimates costs and QALYs for the new treatment and alternative using data that are available at the time.

For example, for LRYGB, based on the results under thresholds of $50,000 and $100,000, the net benefit would be $86,000 and $203,000, respectively for a Female, Age 45, BMI 40 (discount rate = 3% for cost and QALY).

The net benefits stated above would vary depending on the values of our parameter values, such as the coefficients on our utility regression. Our point estimate for the association between an increase in a unit of BMI and utility is -0.00535; but, the 95% confidence interval also includes -0.00400. If we used the latter, the net benefit of our representative patient (at $100,000/QALY threshold) would drop from $203,000 to $167,000. Though the net benefit fell, its magnitude is still high enough to merit coverage.

For the utility parameter, the value of perfect information is low because adding to its precision does not change the fact that the net benefits remain well above generally accepted coverage thresholds. Even if the parameter took a value of 0, so that BMI has no impact on utility, the net benefit would still be $61,000.

The incremental cost-effectiveness ratios (ICERs) of Laparoscopic Roux-en-Y Gastric Bypass (RYGB) relative to no treatment is $13,000, which is well below coverage thresholds. For VOI to be of interest, the ICERs should be close to thresholds, so that uncertainty can result in a different choice between treatment and no treatment. At the current levels, we anticipate VOI to be very low when choosing between bariatric surgery and no surgery.

Going forward, VOI analyses should focus on the choice between Lap GPB and AGB because the outcomes and patient mix are similar. In contrast, GPB patients generally have a different

profile that those undergoing other procedures, thus computing its VOI against alternative surgeries may be intuitively inconsistent.

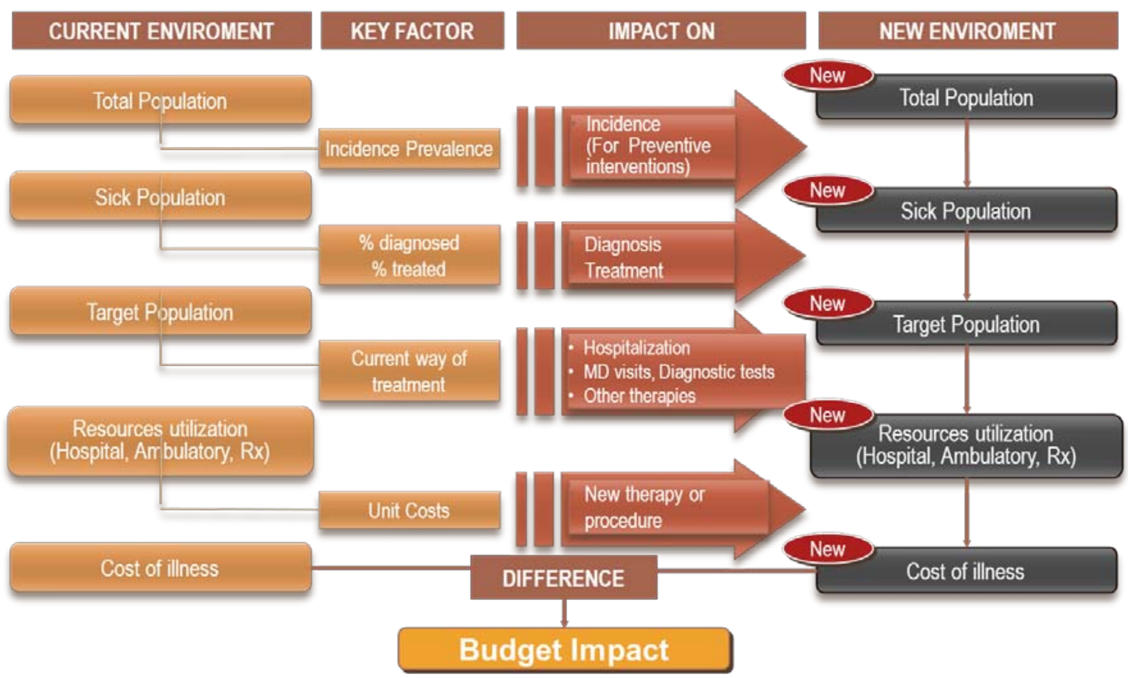
2.3.2 Budget Impact Model

Because of the high cost of surgical procedures for obesity and significant proportion of the population with obesity, the fiscal implications of adopting these interventions must be considered in terms of their overall affordability to payers and the health care system.. For this purpose, we developed a payer-based Budget Impact Model (BIM) to assess the "Monetary Return on Investment (ROI)" for bariatric surgical procedures in obesity as compared to non-operative interventions.

A Budget Impact Model aims to forecast how an increase in the use of bariatric surgery intervention would affect total spending within a defined population for limited time period.. This information can be used for budget planning and for computing the impact of health technology changes on premiums in health insurance schemes. Thus, it will be valuable to decision makers (i.e., administrators of health care programs, administrators of private insurance plans health management organizations, and employers who pay for employee health benefits). The projected impact will depend on the characteristics of a plan's population and the mix of interventions used (Figure 8).

In general, a Budget Impact Model will compare the characteristics of a given population, the resource utilization, and the cost of illness associated with a specific condition to compare it to the potential changes that the proposed intervention may bring; the difference in the cost of illness will result in the absolute budget impact (Figure 8).

Figure 8. Schematic representation of the budget impact analysis (adapted from International Society for Pharmacoeconomics and Outcomes Research [ISPOR] guidelines)



Source: International Society for Pharmacoeconomics and Outcomes Research [ISPOR] guidelines

The purpose of this BIM is to project the monetary consequences of adoption of different types of bariatric surgeries within a specific health care setting. The BIM can provide cost estimates of the management of obesity and its complications in patients eligible for bariatric surgery, and the impact of the potential use of different health care interventions, including but not limited to:

- Non-surgical interventions
- Surgical Interventions for Obesity:
  - Open Roux en Y Gastric Bypass (ORYGB)
  - Laparoscopic Roux en Y Gastric Bypass (LRYGB)
  - Adjustable Gastric Band (AGB)
  - Sleeve Gastrectomy
  - Biliopancreatic diversion

The BIM is flexible enough to use the information provided by the payer or insurer (if available) in conjunction with estimates from our own data analysis or literature reviews. If the payer or insurer does not have specific information about its population, we provide default "best" available estimates from multiple sources. The annual costs are estimated from the BOOM Cost-effectiveness model, which uses information from GHC, Medicare, and MEPS; Population distributions and characteristics are from NHANES or TRICARE-AF databases. The distribution of the procedure mix and other information not found in the available datasets come from the literature, as explained below in each section. The perspective used for the analysis of the BIM is from the payer for a 10-year time horizon, and the outcomes are summarized in annual and cumulative costs, and Per Member per Month Costs (PMPM) to estimate the Return on Investment (ROI) (Table 4).

Table 4. Characteristics and data sources

Data Sources	Perspective	Time Horizon	Outcomes
BOOM Cost-Effectiveness Model GHC Medicare MEPS NHANES TRICARE-AF Literature review	Payer (budget holder)	10 years	Annual and incremental Per Member Per Month (PMPM) Return on investment (ROI)

Source: BOOM Research

The BIM can be customized based on the characteristics of the population of interest (i.e., number of lives covered, age, gender, and body mass index) and characteristics of the interventions (i.e., different types of bariatric surgeries and/or different degrees of use of each

procedure). Since each bariatric procedure has different costs, and may be associated with different levels of weight loss and complications, the inputs used for the costs, complications, and mortality rates, are derived from the cost-effectiveness model, as described above.

The BIM is divided into four main sections:

- Population size and characteristics
- Eligibility criteria and mix of surgical procedures (procedure mix)
- Data from the cost-effectiveness model on costs
- Findings

Population Size and Characteristics: The first step in determining the budget impact of any intervention is to identify the characteristics of the entire population from which those eligible subjects for bariatric surgery will be selected. The current eligibility criteria for bariatric surgery are considered: a) morbid obesity (BMI>40 kg/m2) and b) obese with co-morbidities (BMI>35 with a concomitant disease such as diabetes mellitus, sleep apnea, etc). If the payer or insurer does not have the specific detailed information about their population, we provide a nationally representative distribution of the US population as a reference in our BIM, based on the NHANES report.[64] There is also the alternative to include or exclude subjects over 65 years of age from the analysis. (Figure 9).

Figure 9. Snapshot from the BIM for the population characteristics

Population characteristics

Total number of members: 1,000,000

Use defaults including >65 y | Use defaults excluding >65 y

Females: 53% | 530,207

BMI category

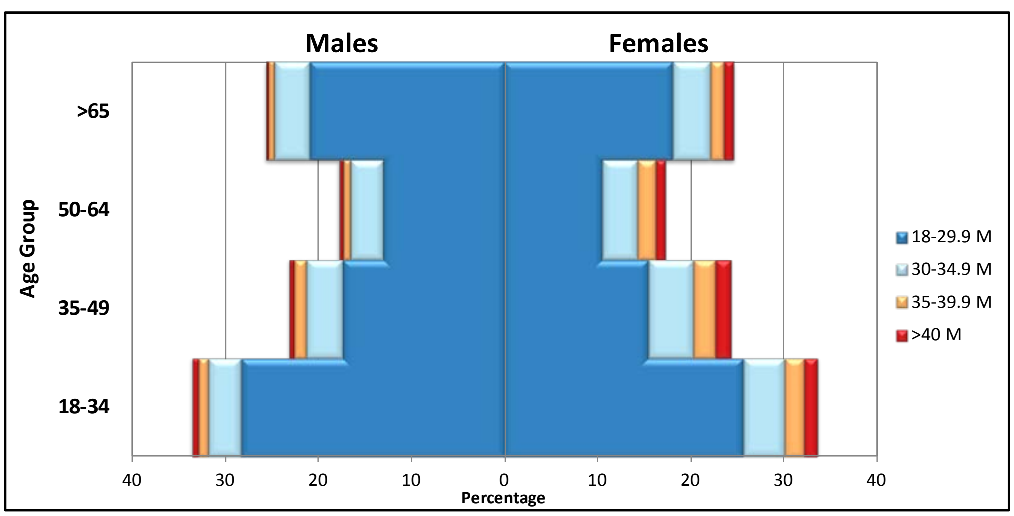
Age group	18-24.9	25-29.9	30-34.9	35-39.9	40-44.9	45-49.9	50<
18-34	17.50%	8.22%	4.44%	2.01%	0.96%	0.28%	0.27%
35-49	8.18%	7.29%	4.83%	2.34%	0.97%	0.36%	0.36%
50-64	4.74%	5.80%	3.82%	1.90%	0.64%	0.23%	0.17%
>65	9.16%	8.93%	4.07%	1.48%	0.50%	0.23%	0.33%

Males: 47% | 469,793

BMI category

Age group	18-24.9	25-29.9	30-34.9	35-39.9	40-44.9	45-49.9	50<
18-34	17.44%	10.82%	3.53%	1.05%	0.30%	0.17%	0.17%
35-49	7.72%	9.71%	3.94%	1.22%	0.38%	0.05%	0.09%
50-64	5.25%	7.80%	3.62%	0.76%	0.22%	0.09%	0.07%
>65	9.85%	11.13%	3.71%	0.65%	0.15%	0.02%	0.10%

Reference: NHANES III



Accept Changes

Source: BOOM Research, Flegal et al.[64]

Eligibility: Once the characteristics of the plan population have been established, those eligible for bariatric surgery, as well as those who are actually receiving the procedure are accounted for in the analysis. If those figures are not available, we provide default values from nationally

representative sources. According to a recent publication by Martin et al.,[65] about 12.6% of the adult population between 18 to 65 years old in the U.S. could be eligible for bariatric surgery based on the National Institutes of Health criteria.[66] BMI between 35 and 39.9 kg/m^2 was present in approximately 16.4 million persons, and approximately 69% of them had more than one comorbidity. BMI >40 kg/m^2 was identified in approximately 10.8 million individuals in this population. In our model, these calculations are performed automatically when the population characteristics are provided. The example shown in Figure 10 represents the distribution of subjects in a hypothetical cohort of 1 million individuals with the same characteristics as a representative sample of the U.S. population according to the NHANES

Figure 10. Sample snapshot of the percentage and total number of subjects eligible for bariatric surgery according to the specific characteristics of the population

Females

Percent of patients eligible for Bariatric surgery in given year

	%	**Number**
BMI >35&<40 with comorbidities	4.5%	23,492
BMI >40	4.0%	20,928
Others	0.0%	-
Total number of patients	**8.6%**	**44,420**

Males

Percent of patients eligible for Bariatric surgery in given year

	%	**Number**
BMI >35&<40 with comorbidities	2.4%	11,331
BMI >40	1.8%	8,475
Others	0.0%	-
Total number of patients	**4.1%**	**19,805**

Source: BOOM Research

Procedure Mix: Since the availability of surgical procedures may vary across the different institutions, the distribution of procedures (procedure mix) within the plan population are considered and can be adjusted. Martin et al. also estimated the percentage of eligible subjects who receive a bariatric procedure in the U.S. and reported that only 0.4% of those eligible subjects received the procedure in 2006.[65] Previous reports have estimated that the most

common procedure performed in the U.S. is the gastric bypass, including open and laparoscopic techniques: they account for approximately 80 to 92% of the total number of bariatric procedures.[67-68] Adjustable Gastric Banding and other restrictive procedures account for most of the remaining procedures, approximately 10% of the total number of procedures. Using these estimates and the previous information from the population characteristics we estimated the absolute number of procedures and the procedure mix in this hypothetical population (Figure 11).

Figure 11. Rate of bariatric surgery in a given year and procedure mix by gender

Females
Percent of patients undergoing Bariatric surgery in given year

	%	Number
BMI >35&<40 with comorbidities	0.4	94
BMI >40	0.4	84
Others	-	-
Total number of patients	0.4	178

Bariatric surgery procedure mix

	%	Number
Lap RYGB	60	107
Lap Band	10	18
Open RYGB	30	53
Sleeve	-	-
Biliopancreatic Div	-	-
Total	100%	178

Males
Percent of patients undergoing Bariatric surgery in given year

	%	Number
BMI >35&<40 with comorbidities	0.4	45
BMI >40	0.4	34
Others	-	-
Total number of patients	0.4	79

Bariatric surgery procedure mix

	%	Number
Lap RYGB	60	48
Lap Band	10	8
Open RYGB	30	24
Sleeve	-	-
Biliopancreatic Div	-	-
Total	100%	79

Source: BOOM Research

Costs: The average annual cost associated with each procedure over at 10-year follow-up horizon is calculated from the results of Cost-Effectiveness Model using the reference patient described

above (42 year old female with BMI of 40 kg/m^2). These annual costs in each year are multiplied by the number of subjects receiving each procedure as determined in the procedure mix shown above, and adjusted by the mortality associated with each procedure, also from the results from the Cost-Effectiveness Model (Table 5).

Table 5. Average annual costs by intervention from the CEM

Total Costs	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
None	$4,101	$4,208	$4,314	$4,420	$4,525	$4,631	$4,736	$4,840	$4,945	$5,048
Lap RYGB	$34,747	$7,177	$10,764	$11,438	$6,615	$3,812	$3,928.84	$4,044	$4,159	$4,274
Lap Band	$21,179	$19,839	$5,683	$5,683	$5,683	$4,083	$4,194	$4,306	$4,416	$4,526
Open RYGB	$36,610	$12,589	$14,047	$12,410	$12,358	$3,812	$3,928.84	$4,044	$4,159	$4,274
Sleeve										
Biliopancreatic Div										

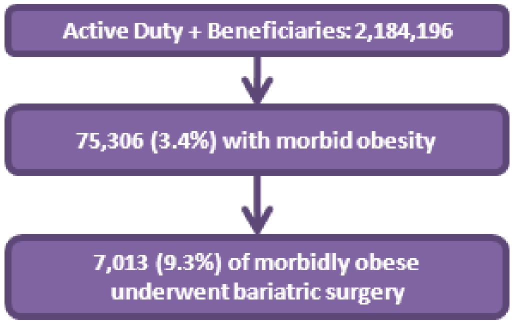
Source: BOOM Research

Findings: Using the previous information and the baseline information from the payer or insurer, the summary information and the results of the calculations is provided in a single table, including the incremental Per Member Per Year (PMPY).

Average annual costs per patients for each procedure are multiplied by the number of eligible subjects receiving the specific procedure. These costs are projected and accumulated over a 10-year period, and compared to the cumulative costs of eligible subjects for bariatric surgery who did not receive the procedure. Results are expressed as the increment of total costs PMPY. By examining different scenarios, with different levels of eligibility and mix of surgical procedures, decision makers could estimate accurately the ROI associated with each alternative over time.

For our reference case, we examined the TRICARE AF database (2001-2007) to determine the number of subjects with obesity (based on ICD-9 codes related to obesity) and subjects who underwent bariatric surgery (based on ICD-9 and CPT codes). According to these calculations, approximately 7,013 subjects underwent bariatric surgery out of 75,306 subjects identified with morbid obesity (Figure 12). Using the current estimates of bariatric surgeries performed in eligible patients, which yielded a 9.3% of eligible subjects undergoing bariatric surgery (scenario 1), we created two additional scenarios to assume that the percentage of bariatric procedures performed in the eligible population could be increased to 15% (scenario 2) or 20% (scenario 3) to estimate their financial impact. The distribution of subjects undergoing each one of the different interventions (procedure mix) was held constant based on the reports from the literature, excluding sleeve gastrectomies and biliopancreatic diversions because of a lack of information on costs during the follow up.[67-68] According to our calculations, in this simulation, approximately 7,013 subjects (9.3%) would receive a bariatric procedure in Scenario 1—most of them a LRYGB (60%), followed by ORYGB in 30%, and the remaining 10% an AGB. For scenarios 2 and 3, an increase of approximately 4,000 procedures and 7,800 procedures are calculated respectively, compared to the scenario 1 (Table 6).

Figure 12. Distribution of the population in the TRICARE-AF database



Source: BOOM Research, TRICARE Data

Table 6. Distribution of patients receiving the interventions by scenario

% of bariatric surgery for eligible patients	**Scenario 1 (9.3% - current)**		**Scenario 2 (15%)**		**Scenario 3 (20%)**	
Procedures	N	%	N	%	N	%
Lap RYGB	4,208	60	6,684	60	8,912	60
AGB	701	10	1,114	10	1,485	10
Open RYGB	2,104	30	3,342	30	4,456	30
Sleeve	-	-	-	-	-	-
Biliopancreatic Div	-	-	-	-	-	-
Total	**7,013**	**100**	**11,140**	**100**	**14,853**	**100**

Source: BOOM Research, TRICARE Data

The percentage of subjects eligible and receiving the bariatric procedures were estimated using information from the database, as well as the distribution of the procedure mix, excluding sleeve gastrectomies and biliopancreatic diversions because of a lack of information on costs during the follow up.[67-68] According to our calculations, in this simulation, approximately 7,013 subjects (9.3%) would receive a bariatric procedure in Scenario 1—most of them a LRYGB (60%), followed by ORYGB in 30%, and the remaining 10% an AGB. For scenarios 2 and 3, an increase of approximately 4,000 procedures and 7,800 procedures are calculated respectively, compared to the scenario 1.

The average annual costs per patient were extracted from the Cost-Effectiveness Model, as described above. Bariatric procedures have the highest costs during the first year of the procedure, but their average annual cost declines over the 10, while the costs associated with the subjects who did not receive the surgery do not changes significantly over time. Once the individual costs are multiplied by the number of subjects receiving each procedure and adjusted by the background mortality of the population, the total costs per year per procedure are estimated. Additional analyses suggest that the number of subjects in each category and the average cost per year are the main drivers of total costs.

In Table 7, we report the incremental PMPY of these interventions, which represents the difference in costs between the group of subjects receiving bariatric surgery and those who did not averaged over the total population included in the simulation. This can be interpreted as the additional cost per member per year that has to be incurred to cover an intervention. In this case, the incremental PMPY becomes negative after the fifth year, leading to a ROI by the sixth year after the implementation of the bariatric surgery in all three scenarios. These results are influenced by many factors included in the model, but are mainly driven by the number of subjects receiving each of the different procedures and the incremental costs associated with each one over time.

Using the TRICARE-AF population, the projected direct medical costs attributable to obese subjects eligible to have a bariatric surgery would surpass $3.3 billion dollars over a period of 10 years. With the current percentage of eligible subjects receiving bariatric surgery in this population (Scenario 1), the total cost of the population undergoing the procedure represents 42% of the total plan costs attributable to morbid obesity during the first year after the procedure. Five years later this population will represent 13%, and by the end of the 10th year they represent 8% of the total direct medical costs attributable to morbid obesity (Table 7).

By increasing the number of subjects undergoing bariatric surgery, the direct medical costs are increased further, but the savings in the incremental PMPY cost are also increased after the 5th year. In this population, when the percentage of patients undergoing bariatric surgery increases to 15%, the total direct medical costs at the end of the 10th year are only increased by 6% compared to the current scenario. In this population, when the percentage of patients undergoing bariatric surgery increases to 20%, the total direct medical costs at the end of the 10th year are only increased by 11% compared to the current scenario.

The cumulative total cost of the group who received the procedure compared to the group who did not show important differences overtime. By comparing the groups by each of the different scenarios examined, we observed a change in the slope of the cumulative costs curve in the group of subjects who received the procedures (Figure 13).

Table 7. Estimated annual plan costs by each scenario and by the population receiving or not the procedure in year 1.

	BUDGET IMPACT CALCULATIONS	Total cost of the population without the procedures	Total cost of the population undergoing procedures	Total cost of the population if the intervention is not available	Total plan costs	Incremental PMPY
Scenario 1 (9.3%)	Year 1	$ 274,920,754	$ 233,203,218	$ 303,588,241	$ 508,123,972	$ 94
	Year 2	$ 281,994,567	$ 70,404,309	$ 311,399,678	$ 352,398,876	$ 19
	Year 3	$ 289,019,083	$ 78,576,120	$ 319,156,679	$ 367,595,204	$ 23
	Year 4	$ 296,050,293	$ 77,618,905	$ 326,921,072	$ 373,669,198	$ 22
	Year 5	$ 303,028,801	$ 57,630,193	$ 334,627,267	$ 360,658,994	$ 12
	Year 6	$ 310,014,783	$ 26,824,054	$ 342,341,715	$ 336,838,837	$ (3)
	Year 7	$ 316,944,665	$ 27,631,329	$ 349,994,214	$ 344,575,995	$ (3)
	Year 8	$ 323,782,459	$ 28,428,245	$ 357,545,022	$ 352,210,704	$ (3)
	Year 9	$ 330,690,254	$ 29,217,807	$ 365,173,130	$ 359,908,061	$ (3)
	Year 10	$ 337,502,597	$ 30,007,596	$ 372,695,834	$ 367,510,193	$ (3)
Scenario 2 (15%)	Year 1	$ 258,050,005	$ 370,442,772	$ 303,588,241	$ 628,492,777	$ 150
	Year 2	$ 264,689,726	$ 111,837,082	$ 311,399,678	$ 376,526,809	$ 30
	Year 3	$ 271,283,177	$ 124,817,986	$ 319,156,679	$ 396,101,163	$ 36
	Year 4	$ 277,882,911	$ 123,297,451	$ 326,921,072	$ 401,180,363	$ 35
	Year 5	$ 284,433,177	$ 91,545,429	$ 334,627,267	$ 375,978,605	$ 20
	Year 6	$ 290,990,458	$ 42,609,948	$ 342,341,715	$ 333,600,405	$ (4)
	Year 7	$ 297,495,082	$ 43,892,303	$ 349,994,214	$ 341,387,385	$ (4)
	Year 8	$ 303,913,269	$ 45,158,201	$ 357,545,022	$ 349,071,470	$ (4)
	Year 9	$ 310,397,161	$ 46,412,419	$ 365,173,130	$ 356,809,580	$ (4)
	Year 10	$ 316,791,459	$ 47,666,997	$ 372,695,834	$ 364,458,456	$ (4)
Scenario 3 (20%)	Year 1	$ 242,870,593	$ 493,923,697	$ 303,588,241	$ 736,794,289	$ 200
	Year 2	$ 249,119,743	$ 149,116,109	$ 311,399,678	$ 398,235,852	$ 40
	Year 3	$ 255,325,344	$ 166,423,981	$ 319,156,679	$ 421,749,325	$ 48
	Year 4	$ 261,536,858	$ 164,396,602	$ 326,921,072	$ 425,933,459	$ 47
	Year 5	$ 267,701,813	$ 122,060,571	$ 334,627,267	$ 389,762,385	$ 26
	Year 6	$ 273,873,372	$ 56,813,263	$ 342,341,715	$ 330,686,635	$ (6)
	Year 7	$ 279,995,372	$ 58,523,070	$ 349,994,214	$ 338,518,442	$ (6)
	Year 8	$ 286,036,018	$ 60,210,934	$ 357,545,022	$ 346,246,952	$ (6)
	Year 9	$ 292,138,504	$ 61,883,226	$ 365,173,130	$ 354,021,730	$ (5)
	Year 10	$ 298,156,667	$ 63,555,996	$ 372,695,834	$ 361,712,663	$ (5)

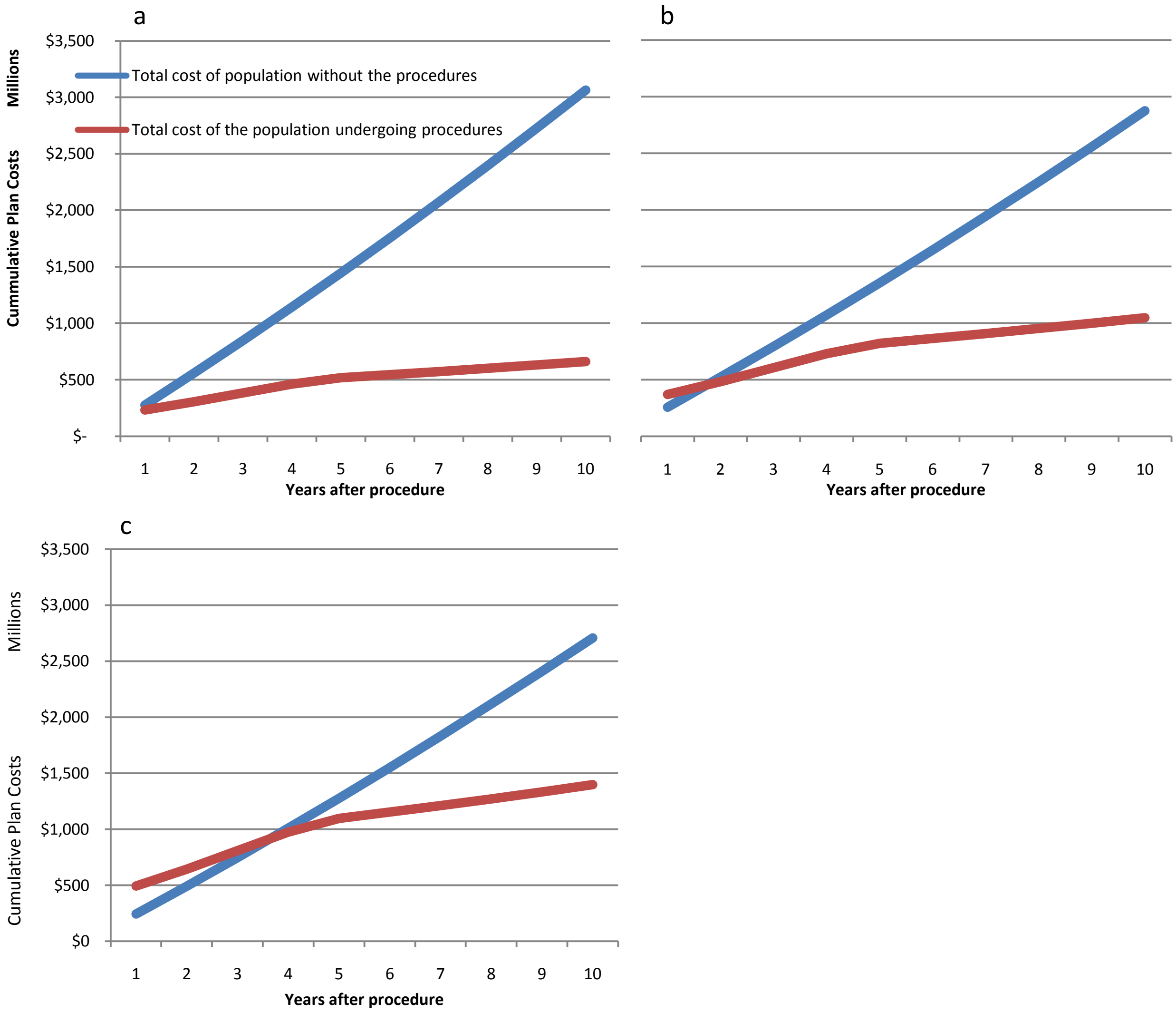
Source: BOOM Research, TRICARE Data

Table 8. Estimated cumulative plan costs by each scenario and by the population receiving or not the procedure in year 1.

	Cumulative costs	Total cost of population without the procedures	Total cost of the population undergoing procedures	Total cost of the population if the intervention is not available	Total cost of the population if the new intervention is available
Scenario 1 (9.3%)	Year 1	$ 274,920,754	$ 233,203,218	$ 303,588,241	$ 508,123,972
	Year 2	$ 556,915,321	$ 303,607,527	$ 614,987,919	$ 860,522,848
	Year 3	$ 845,934,404	$ 382,183,647	$ 934,144,599	$ 1,228,118,051
	Year 4	$ 1,141,984,698	$ 459,802,552	$ 1,261,065,671	$ 1,601,787,250
	Year 5	$ 1,445,013,498	$ 517,432,745	$ 1,595,692,937	$ 1,962,446,244
	Year 6	$ 1,755,028,281	$ 544,256,799	$ 1,938,034,652	$ 2,299,285,080
	Year 7	$ 2,071,972,947	$ 571,888,128	$ 2,288,028,867	$ 2,643,861,075
	Year 8	$ 2,395,755,406	$ 600,316,373	$ 2,645,573,889	$ 2,996,071,779
	Year 9	$ 2,726,445,660	$ 629,534,180	$ 3,010,747,019	$ 3,355,979,840
	Year 10	$ 3,063,948,257	$ 659,541,776	$ 3,383,442,853	$ 3,723,490,033
Scenario 2 (15%)	Year 1	$ 258,050,005	$ 370,442,772	$ 303,588,241	$ 628,492,777
	Year 2	$ 522,739,731	$ 482,279,855	$ 614,987,919	$ 1,005,019,586
	Year 3	$ 794,022,909	$ 607,097,840	$ 934,144,599	$ 1,401,120,749
	Year 4	$ 1,071,905,820	$ 730,395,291	$ 1,261,065,671	$ 1,802,301,112
	Year 5	$ 1,356,338,997	$ 821,940,720	$ 1,595,692,937	$ 2,178,279,717
	Year 6	$ 1,647,329,455	$ 864,550,668	$ 1,938,034,652	$ 2,511,880,122
	Year 7	$ 1,944,824,537	$ 908,442,970	$ 2,288,028,867	$ 2,853,267,507
	Year 8	$ 2,248,737,806	$ 953,601,171	$ 2,645,573,889	$ 3,202,338,977
	Year 9	$ 2,559,134,967	$ 1,000,013,591	$ 3,010,747,019	$ 3,559,148,557
	Year 10	$ 2,875,926,425	$ 1,047,680,588	$ 3,383,442,853	$ 3,923,607,013
Scenario 3 (20%)	Year 1	$ 242,870,593	$ 493,923,697	$ 303,588,241	$ 736,794,289
	Year 2	$ 491,990,335	$ 643,039,806	$ 614,987,919	$ 1,135,030,141
	Year 3	$ 747,315,679	$ 809,463,787	$ 934,144,599	$ 1,556,779,466
	Year 4	$ 1,008,852,537	$ 973,860,389	$ 1,261,065,671	$ 1,982,712,925
	Year 5	$ 1,276,554,350	$ 1,095,920,960	$ 1,595,692,937	$ 2,372,475,310
	Year 6	$ 1,550,427,722	$ 1,152,734,224	$ 1,938,034,652	$ 2,703,161,945
	Year 7	$ 1,830,423,093	$ 1,211,257,294	$ 2,288,028,867	$ 3,041,680,387
	Year 8	$ 2,116,459,111	$ 1,271,468,228	$ 2,645,573,889	$ 3,387,927,340
	Year 9	$ 2,408,597,616	$ 1,333,351,454	$ 3,010,747,019	$ 3,741,949,070
	Year 10	$ 2,706,754,283	$ 1,396,907,451	$ 3,383,442,853	$ 4,103,661,733

Source: BOOM Research, TRICARE Data

Figure 13. (a) Scenario 1: Cumulative direct medical costs of subjects receiving the intervention (9.3%) compared to the group of eligible subjects not receiving the intervention. (b) Scenario 2: Cumulative direct medical costs of subjects receiving the intervention (15%) compared to the group of eligible subjects not receiving the intervention. (c) Scenario 3: Cumulative direct medical costs of subjects receiving the intervention (20%) compared to the group of eligible subjects not receiving the intervention.



Source: BOOM Research, TRICARE Data

2.4 Adjustable Gastric Banding Survey (AGB) Study

Critical, population-level information about the adjustable gastric band procedure was not available to help inform certain components of the model. We conducted a primary data collection study to evaluate healthcare utilization and quality of life in patients with an Adjustable Gastric Band (AGB). The AGB procedure is a relatively new surgical treatment for obesity in the United States; billing codes for the procedure did not become effective until January 1, 2006.[69] AGB procedures require frequent outpatient visits and medical resource utilization in the first three years after surgery, however, given the recent implementation of AGB in the U.S. there was no detailed information about follow-up care and outcomes to-date in either the literature or administrative datasets screened for use in this study. Recognizing the importance of this data, investigators gained approval to create a data source specifically related to post-surgical AGB inpatient and outpatient care, outcomes, and quality of life.

Population and Design: Eligible participants were patients aged 18 years or older who had undergone AGB at inpatient and outpatient surgical centers across Washington State. Patients were identified by obtaining operative case lists from the medical centers and contacted by mail with the request to complete a survey evaluating healthcare utilization and EQ-5D Quality of Life survey. The mailing included an information statement informing patients about the study objectives and inviting their voluntary participation, survey instruments and a stamped return envelope. As an incentive, a $2 bill was included with the first mailing to encourage patients to complete and return the survey materials. Patients who did not return survey within 30 days were mailed a second survey and those who did not return the second survey within 30 days were mailed a third. Patients who were unresponsive to three paper surveys were mailed a postcard with a link to an online version of the survey. Patients were not re-contacted following the fourth attempt by postcard.

Data Elements: AGB surgical information, follow-up care, health, and EQ-5D data were collected. Participants self-reported status currently and/or retrospectively.

Some of the main survey variables include:

- Height and weight – at surgery and current
- Number of AGB adjustments in the last year
- Additional AGB-related surgeries
- Conditions – before and post AGB surgery

In addition, participants completed the EQ-5D and the EQ VAS. The EQ-5D is a 5-item instrument intended to measure health outcomes for a wide range of health treatments and conditions. The dimensions include mobility, self-care, usual care, pain/discomfort, and anxiety/depression. The EQ VAS is a rating of health-related Quality of Life. The participant will rate his or her health state by marking the appropriate point on the EQ VAS, a graphical representation of the value of health on a standard scale 20 centimeters in length. The scale ranges 0-100 where 0 is the worst state imaginable and 100 is the best state imaginable.[70]

Uses and Limitations: The AGB primary data collection study offered an important opportunity to examine 1-2 year AGB outcomes that had not been evaluated or reported to-date. Currently,

there are no billing codes for AGB adjustments.[71] The AGB study provided information about follow-up care that cannot be assessed using claims data. Further, it provided pre and post information and patient reported outcomes (quality of life) that are not reported through administrative datasets but are important to understanding the cost-to-benefit ratio for surgical treatment of obesity.

There are some limitations to the data. First, the participants were not selected at random and self selected to participate which may result in bias. For example, patients who chose to participate may have been more compliant with their treatment and/or had better outcomes. However, four attempts were made to encourage participation. Second, the longitudinal data points were collected at one time point for current status and retrospectively. In general, there are limitations to retrospective recall. However, the health conditions assessed are serious, and as such, are less vulnerable to recall problems.

<u>AGB Study Outcomes:</u> The AGB survey study included 1,556 patients who had AGB bariatric operation between April 1, 2007 and July 1, 2008 at four sites in Washington State. As of August 2010, the overall response rate was 32% (502 responded). Response rates ranged across sites from 25% to 64%.

Of the respondents, 96.6% had an adjustment since AGB placement (485 respondents), 2.6% did not have an adjustment since placement (13 respondents) and 0.8% did not respond (4 missing). In the last year, 36.3% of the respondents had 0 adjustments (176 respondents), 20.1% had 1 adjustment (101 respondents), 34.9% had 2 to 6 adjustments (175 respondents), 3.2% had more than 6 adjustments (16 respondents) and 3.5% did not respond (17 missing). Recommended care is 6 adjustments in the first year after placement.

Of the 502 patients that responded to the survey, 15% had an additional operation related to the original AGB placement (73 respondents), 3.6% had a band-port-tubing revision following their original AGB placement (18 respondents), 2.4% had a band replacement (12 respondents), 4% had a band removal (20 respondents), 2.2% had a conversion to another bariatric surgery (11 respondents) and 2.4% had another operation not listed on the survey (12 respondents).

3. KEY RESEARCH ACCOMPLISHMENTS

- Reviewed 14 and ultimately acquired 6 administrative and clinical datasets from which we created a comprehensive relational and normative dataset used to inform and populate the Cost Effectiveness and Budget Impact Models

- Mined over 9,500 articles from PubMed and tabulated roughly 125 relevant pieces into an easily searchable report for future inclusion into the Cost Effectiveness and Budget Impact Models

- Quantified the burden of non-surgical, obesity care costs/expenses and outcomes across various regions in the U.S. where the DOD authorizes care, concluding that obesity is a significant driver of costs and QALYs and that a reduction in BMI of obese patients could be associated with lower costs and better quality-adjusted life expectancy

- Quantified the burden of surgical costs/expenses and outcomes across various regions in the U.S. where the DOD authorizes care through the analysis and presentation of patient characteristics, mortality, complications and cost by procedure for Medicare and Medstat beneficiaries (tables included in Appendix 3).

- Developed a cost-effectiveness simulation model that assesses cost-effectiveness for healthcare policy decision-making related to non-operative and operative approaches to obesity and demonstrates that surgical interventions are a cost-effective alternative compared to a non-surgical group, assuming a threshold of $50,000 per QALY gained

- Developed a budget impact model that assesses monetary return on investment for obesity-related operative interventions compared to non-operative interventions and answers the question: at the payer level, what financial impact would coverage for bariatric surgery have on total plan costs?

- Validated results and strength of models through a validation procedure, structural and parameter sensitivity analyses and value-of-information (VOI) analysis

- Conducted a primary data collection study to create a novel dataset evaluating post-operative healthcare utilization and quality of life in patients undergoing AGB, resulting in an overall response rate of 32%

4. REPORTABLE OUTCOMES

- "Projecting the economic outcomes of obesity using a natural history model." Poster presented at ISPOR - International Society for Pharmacoeconomics and Outcomes Research: 15th Annual International Meeting. *May 15-19, 2010. Atlanta, GA*

- "Budget Impact Analysis of Bariatric Surgery for Morbid Obesity." Presentation at AFMS Medical Research Symposium. *August 24-26, 2010. Arlington, VA* (abstract in appendix 4)

- "The Impact of Medicare's Accreditation-based National Coverage Decision on the Use, Safety and Cost of Bariatric Surgery among Medicare Beneficiaries." *Publication submitted to* Annals of Surgery

5. CONCLUSIONS

Nearly a third of all Americans are obese. Obesity and related disorders like diabetes and cardiovascular disease are a leading cause of preventable death in the US. Surgical interventions such as gastric bypass and adjustable banding procedures offer the potential for significant and sustained weight loss and reversal of associated conditions, and may even reduce the risk of death. These interventions also come at significant financial cost, have variable success and are still being evaluated to determine their appropriate place amongst other emerging strategies to combat obesity from a population-health perspective. Non-surgical interventions such as behavioral change, diet and exercise, and medications do not result in sustained and significant weight loss. The evidence suggests that these other interventions have variable success, offer a non-invasive approach, and are viewed by many as being less costly (at least in the short run) than surgical approaches. Bariatric surgical procedures have been shown in several studies to be an effective long-term strategy for the treatment of morbid obesity. Thus, this study sought to (1) define the clinical impact and economic burden of bariatric surgical procedures, and (2) estimate the cost-effectiveness and budgetary impact of obesity treatments when compared to no surgical intervention.

We developed two economic evaluation models to compare bariatric surgical procedures to non-operative approaches for morbid obesity. The cost-effectiveness model assessed the cost and health impact following bariatric surgery over the patient's remaining lifetime. Following weight loss from the procedure, the model projected the trajectory of weight change over the rest of life. Cost impacts were measured from the payer's perspective, and health impacts were measured in terms of quality-adjusted life years. For patients eligible for bariatric surgery under current guidelines (BMI > 35 + co-morbidities and BMI > 40), the model accounted for baseline weight, age, and gender and was estimated using data from clinical trials, several national surveys, literature, and public and private payer databases. Reference case and sensitivity analyses (both parametric and structural) were conducted to estimate the incremental cost-effectiveness ratio (ICER) for each of three surgical procedures— open roux en Y gastric bypass (ORYGB), laparoscopic roux en Y gastric bypass (LRYGB), and adjustable gastric banding (AGB)—in terms of cost per QALY gained. A payer-based budgetary impact model (BIM) also was developed to estimate impact on health plan costs over a ten-year horizon for a fixed cohort of bariatric patients. This provides an indicator of the short-term return on investment, i.e., time to achieving net cost savings. Annual costs estimates used in the BIM were derived from the cost-effectiveness simulations and applied to hypothetical health plan patient and standard coverage characteristics, which can be adjusted by users of the model. The reference case BIM results were simulated for the TRICARE Air Force population to illustrate the utility and flexibility of the model.

For the reference case in the cost-effectiveness analysis, we simulated discounted outcomes, costs and QALYs for a 45 year-old female with a baseline BMI of 40 kg/m^2. Assuming a conservative cost-effectiveness threshold of $50,000 dollars per QALY gained in the US, all of the surgical interventions are cost-effective when compared to non-surgical approaches. Sensitivity analyses showed that the modeled ICERs were sensitive to plausible variation in key clinical and cost values, although none of the analyses changed the overall policy conclusions. The budget impact of adding coverage for bariatric surgical procedures increases medical costs

to TRICARE AF in the first four years, but reaches a break-even point at five years and leads to lowers costs beyond that time.

We find that bariatric surgery for morbid obesity is cost-effective and is likely to produce long-term cost-saving opportunities for payers, including the Air Force. Economic assessment models can support clinicians, payers, and patients in making clinical and health policy decisions about expanding health plan coverage for bariatric surgical procedures for morbid obesity.

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7. APPENDICES

Acronyms and Symbols
Description of Datasets
Descriptive Outcomes: The burden of surgical costs/expenses and outcomes
Budget Impact Analysis of Bariatric Surgery for Morbid Obesity Abstract
Award Beneficiaries

<u>Appendix 1</u>
Acronyms and Symbols

AD – Active Duty
AF – Air Force
AFDW – Air Force District of Washington
AGB – Adjustable Gastric Band
AHRQ – Agency for Healthcare Resource and Quality
ARPA – Appointment/Registration/Patient Accounting
BCSP – Breast Cancer Surveillance Program
BIM – Budget Impact Model
BMI – Body Mass Index
BOOM – Bariatric Outcomes and Obesity Modeling
CAPI – Computer Assisted Personal Interviewing
CDC – Centers for Disease Control and Prevention
CEM – Cost-Effectiveness Model
COB – Coordination of Benefits
COBRA – Consolidated Omnibus Budget Reconciliation Act
COPAY – Copayment
CPI – Consumer Price Index
DEERS – Defense Enrollment Eligibility Reporting System
DHHS – Department of Health and Human Services
DOD – Department of Defense
DRG – Diagnosis Related Group
EMR – Electronic Medical Record
GHC – Group Health Cooperative
HLM – Hierarchical Linear Models
HMO – Health Maintenance Organization
ICER – Incremental Cost-Effectiveness Ratio
IRB – Institutional Review Board
ISPOR - International Society for Pharmacoeconomics and Outcomes Research
LOS – Length of Stay
LRYGB – Laparoscopic Roux en Y Gastric Bypass
MDC – Major Diagnostic Category
MEDPAR – Medicare Provider Analysis and Review
MEPS – Medical Expenditure Panel Survey
MEPS-HC – Medical Expenditure Panel Survey Household Component
MEPS-IC – Medical Expenditure Panel Survey Insurance Component
MFP – Multivariable Fractional Polynomials
NCHS – National Center for Health Statistics
NDI – National Death Index
NHANES – National Health and Nutrition Examination Survey
NHIS – National Health Interview Survey
OLS – Ordinary Least Squares
ORYGB – Open Roux en Y Gastric Bypass
PAY – Payment

PLOS – Prolonged Length of Stay
PMPY – Per Member Per Year
PSA – Probability Sensitivity Analysis
PSU – Primary Sampling Unit
QALY – Quality Adjusted Life Year
ROI – Return on Investment
RYGB – Roux-en-Y Gastric Bypass
SCOAP – Surgical Care and Outcomes Assessment Program
UW – University of Washington
VOI – Value of Information
YLG – Years of Life Gained

Appendix 2
Description of Datasets

1. Air Force TRICARE

1.1 Description

TRICARE is the health care program for the U.S. military. TRICARE supplements the health care resources of the uniformed services with networks of civilian providers. TRICARE beneficiaries have 3 main health coverage options. They include TRICARE Prime, TRICARE Standard, and TRICARE Extra. TRICARE Prime is similar to an HMO benefit primarily for beneficiaries younger than 65 and administered through military treatment facilities. TRICARE Standard is a fee-for-service benefit. Beneficiaries can obtain care from a TRICARE-authorized provider (network or non-network) but will pay higher out-of-pocket costs. TRICARE Extra is similar to a PPO benefit. There is also TRICARE for Life, a secondary coverage benefit for Medicare-eligible retirees and their dependents age 65 years and older. Retirees can choose TRICARE or Veteran Administration benefits.[72-73]

1.2 Population and Design

There are approximately 9.4 million eligible beneficiaries registered with the Defense Enrollment Eligibility Reporting System (DEERS).[74] Air Force enrolled beneficiaries including active duty service members, reserves, retirees, and their dependents will be eligible for analysis.

The data available for this project vary by year. Surgical and non-surgical cohorts will be constructed based on the availability of data. Active duty (AD) obese and non-surgical persons will be based on both annual physical data and medical records.

Data available by year:

- TRICARE medical records available 2001-2007
- AD annual physical data available 1997-2007 (BMI)
- Military AD personnel data available 2001-2007 (demographic)
- Beneficiary enrollment data available 2001-2007 (age and sex)
- Beneficiary eligibility data available 2004-2007 (demographic)

1.3 Data Elements

Data from Enrollment, Annual Physical (AD only), Direct Inpatient, Direct Outpatient, Prescription (RX), Lab, Network Inpatient, and Network Outpatient files will be used.

Some of the main data elements include:

- Demographic
- Enrollment – dates and coverage
- Height and weight (from AD annual physicals)
- Inpatient/Outpatient – dates, diagnoses, procedures
- Lab results for tests of interest (e.g. glucose, cholesterol)
- Outpatient Prescriptions

1.4 Uses and Limitations

The AF population will assist in better understanding the differences between the civilian and non-civilian populations in terms of BMI and health outcomes. It is expected that some differences may exist. For example, active duty military and civilians with higher BMIs likely differ in percent of body fat and, therefore, may differ in health outcomes. Analysis of the non-civilians is also an opportunity to examine a population with equal access to health care [73]

2. Group Health Cooperative

2.1 Description

Group Health, with headquarters in Seattle, Washington, is a large mixed-model, nonprofit, health plan and care system founded in 1947. Group Health is one of the few consumer-governed nonprofit health care cooperatives in the nation. Group Health serves 20 of the 39 Washington counties and two counties in North Idaho. As of May 2009, the Group Health system included approximately 607,000 members.

Group Health provides comprehensive health care through its own facilities including 25 primary care or family medical centers; 6 specialty medical centers, 8 behavioral health clinics, 15 vision centers, 6 speech, language and learning centers and 2 hospitals. More than 70 percent of members receive care in Group Health–owned medical facilities. Group Health has affiliations with 39 other major institutions that meet Group Health standards and follow its protocols when there is a need for selected specialty services unavailable at Group Health or in locations where Group Health has no hospitals. Most Group Health staff work in primary-care medical centers owned by Group Health. Group Health employs 1,244 (821 full time employees [FTE]) providers including 45 specialists and sub-specialists, the majority of whom are board certified (95% family practice, 93% pediatrics, 96% obstetrics/gynecology; 94% other specialties). Group Health also contracts with 9,100 independent doctors and group practices throughout the state. Group Health provides primary, specialty, hospital, home health, and inpatient skilled nursing care on a pre-paid (capitation) basis.

2.2 Population and Design

Group Health enrollees are diverse: As of January 2008, enrollment totals include approximately 55,580 Medicare beneficiaries; 15,987 members enrolled through a state healthcare plan (Healthy Options); 47,744 federal government employees; 98,084 state government enrollees and 320,000 in commercial, individual or other plans. Minority representation among Group Health members (13.5%) is similar to that of Washington State (15.1%). The proportion of Group Health members who are Asian/Pacific Islander (6.7%) is higher than the U.S. population (3.7%) and similar to Washington State (7.4%). The proportion of African Americans at Group Health (5%) is also similar to Washington State (4%). We estimate our study enrollment to be similar to the overall Group Health member population.

We will extract comprehensive clinical health care use data on all bariatric surgery cases and all individuals with a body mass index ≥ 35 kg/m2 at Group Health.

2.3 Data Elements and Automated Data Sources

Data from the following Group Health systems will be used:

- Clinical Information Systems;

- ARPA (Appointment/Registration/Patient Accounting);
- Death Files;
- Decision Information Support Center;
- Unified Hospital File;
- Membership/Enrollment Files;
- Pharmacy System;
- Breast Cancer Surveillance Program (BCSP) database

These data systems will be utilized to assess claims (diagnosis and procedure codes from inpatient hospital stays, hospital ambulatory services, emergency room care, and outpatient clinic visits at non-Group Health facilities); costs (capture and fully allocate health service delivery costs of all internal services provided directly by Group Health as well as claims for covered services that enrollees receive from contracted providers); emergent or urgent care (treatment record forms from medical evaluation at outside or non-contract sites); pharmacy (detailed information on the fill date, quantity dispensed, route, strength and dispenser); population counts (population data are available for western Washington and for Group Health. Group Health population counts by age, gender, year and county are available from enrollment files); and registration (information on each outpatient visit an enrollee makes to a Group Health provider including primary care, specialty, mental health, emergency and ancillary services). Additionally, Group Health's Breast Cancer Surveillance Program (BCSP) database will be used to extract self-reported height and weight data among women age 40 and older who completed this annual survey to construct a data cohort of patient evaluating natural changes of BMI and clinical conditions over time.

2.4 Uses and Limitations

Group Health has fully implemented EpicCare as its Electronic Medical Record System (EMR) in all the clinics and Specialty Centers it owns and operates. Group Health Center for Health Studies' ability to access and abstract data from both the historical paper records and the prospective computer based records is a valuable asset for records-based research studies. The Group Health Database will capture longitudinal data on bariatric cases from 1995 through 2008 and will uniquely be able to link those cases to data on laboratory use, pharmacy use, survival, body weight (2003-2008 from EMR and 1980-2008 from Breast Cancer Surveillance Program), and inpatient and outpatient health care use and claims. The main advantage of the Group Health database is its ability to accurately identify non-operative severely obese control patients using heights and weights collected in the electronic medical record. These control patients will also be linked to comprehensive data on laboratory use, pharmacy use, survival, body weight (2003-2008 from EMR and 1980-2008 from Breast Cancer Surveillance Program), and inpatient and outpatient health care use and claims.

The main limitations of the Group Health databases are the following: Group Health data come from a single, mixed-model health care delivery system in the Pacific Northwest; thus, findings from this population may not be completely generalizable to other areas of the United States with different populations and systems of care. The body weight and height data from Group Health come from two sources, but the most accurate source of this data (our EMR) is limited to the

years 2003-2008. The Group Health databases do not contain any information on self-reported quality of life.

3. Medical Expenditure Panel Survey

3.1 Description

The Medical Expenditure Panel Survey (MEPS) is a set of surveys about health services in the U.S. MEPS data consists of two main components, the Household Component (MEPS-HC) and the Insurance Component (MEPS-IC), and supplemental data from medical providers. The surveys have been conducted annually since 1996. The Household Component is available for public use (Agency for Healthcare Resource and Quality [AHRQ], 2006).

The Household Component contains demographic characteristics, health conditions, health status, health resource utilization, medical expenditures, insurance coverage, access to care, satisfaction with care, income, and employment for each individual in a surveyed household. The Insurance Component or the Health Insurance Cost Study contains data from private and public sector employers on their employee health insurance plans. This data includes the number and types of plans, eligibility, and costs. MEPS also has a Medical Provider Component. Hospitals, physicians, home health care providers, and pharmacies provide information for respondents in the Household Component. This information is incorporated into the Household Component and is not available as a separate file.[75]

3.2 Population and Design – Household Component

The target population for MEPS is the U.S. civilian, non-institutionalized population. Some subpopulations of interest are oversampled (family income less than 200% of the Federal poverty level, blacks, Hispanics and starting in 2006 Asians). All data for a household are reported by a single household member.[76]

The sampling frame is the National Household Interview Survey (NHIS). The NHIS sample design for years 1995-2004 consisted of a stratified multi-stage sample design. The brief outline of steps is as follows:

1. Area sample of Primary Sampling Units (PSUs, typically one or more counties);
2. Within each PSU, density strata were developed using 1990 US Census population distribution data at the block or block group level;
3. Within each density stratum, clusters of housing units were identified;
4. Households within clusters were identified.

Households containing Hispanics and blacks were oversampled at 2 and 1.5 times that of the other households, respectively. There were 358 PSUs for each year between the years 1995-2004. For each year, approximately 76,000 households were selected and approximately 40,000 were interviewed.[76]

The MEPS-HC is a national probability survey with an overlapping panel design. Each year a new panel or sample of households is selected from the NHIS population. In general, NHIS

households are eligible for MEPS if they participated in quarter 1-3 and 2-4 of NHIS panels (i.e. 2 of 4 subdesigns). Each panel participates in 5 rounds of interviews covering 2 years. Except for the first year (1996), data collection is simultaneous for two MEPS panels. Starting in 1997, data are combined for each calendar year (e.g. year 2 for panel 1 and year 1 for panel 2). [76]

Due to Department of Health and Human Services (DHHS) objectives and resources, the MEPS sample size and the number oversampled for subpopulations of interest have varied by year. Starting with 2002, the target sample size for the MEPS-HC is approximately 15,000 households (~37,000 individuals).[76-77]

3.3 Data Elements

Five in-person interviews are conducted over a 2 ½ year period using Computer Assisted Personal Interviewing (CAPI) technology. Interviews, on average, last an hour and a half. Demographic, charges and payments, health status, conditions, utilization, employment, and health insurance information are collected at each interview. Access to care, child preventive health, and satisfaction with insurance and providers are collected at rounds 2 and 4. The EQ-5D and SF-12 were administered at rounds 2 and 4 for years 2000-2003 and 2000-2006 respectively. Assets, income, preventive care, and priority conditions are collected at rounds 3 and 5. BMI is collected at rounds 3 and 5 for years 2001-2006. Height and weight are only collected for adults in year 2000. Diabetes, asthma, hypertension, ischemic heart disease, arthritis, stroke, and COPD are priority conditions. [78]

Questionnaires can be found at:
http://www.meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#Questionnaires

3.4 Uses and Limitations

The survey design allows for the assessment of changes and relationships in health status, income, employment, insurance coverage, health resource utilization, and payment for healthcare over a two year period. Since the data are comparable year to year, these data can also be used to examine long term trends at the event or person level.[75-76]

There are some limitations to the data. Although self-reported conditions are coded by professional coders and the error rates were less than 2.5% for condition coding, the reports are sometimes vague and provided by someone else (i.e. another household member). For this reason, health conditions are not intended for estimating prevalence, however, can be used as covariates.[79]

As the data are publicly available, ICD-9 procedure and diagnosis codes are not detailed. Procedure and diagnosis codes are available as 2 and 3 digit codes respectively. For this reason bariatric surgery cannot be identified and there will be deviations from the traditional calculation of the Charlson co-morbidity index.

4. Medicare

4.1 Description

Medicare is a health insurance program for persons 65 years of age or older; persons under the age of 65 with certain disabilities; and persons with permanent kidney failure. This insurance

program is comprised of 4 parts: (A) hospital insurance, (B) medical insurance, (C) managed care, and (D) prescription drug coverage starting in 2007. Medicare data are available as research identifiable files, limited data sets, and non-identifiable files (Centers for Medicare and Medicaid Services [CMS], 2005).

4.2 Population and Design

The Medicare population consists of persons 65 years of age or older; persons under the age of 65 with certain disabilities; and persons of all ages with permanent kidney failure. A majority of Medicare beneficiaries are 65 or older (approximately 90%). A majority of persons age 65 and older are eligible for Medicare (97%). Nearly all recipients have Part A coverage. Ninety-six percent of elderly Part A beneficiaries enroll in Part B coverage. Nearly all deaths for persons age 65 or older (approximately 99%) are accounted for in Medicare. All beneficiaries who had a bariatric surgery as determined by procedure code in the Carrier file during 2004-2008 were selected. In a recent evaluation of Medicare claims files, our investigators found 16,155 Medicare covered patients underwent bariatric surgical procedures between 1996 and 2002, of which 90.6% were younger than 65 years old.[80]

4.3 Data Elements

Research identifiable files for years 2004-2008 will be obtained for the following files:

- Medicare Provider Analysis and Review (MEDPAR);
- Carrier Claims;
- Outpatient Claims;
- Home Health Agencies;
- Hospice;
- Durable Medical Equipment

These data systems will be utilized to assess healthcare services for short stay, long stay and skilled nursing hospitalizations; physician and suppliers; institutional outpatient provider claims for healthcare services; home health agencies; and final action claims for healthcare devices and diagnostics purchased.

4.4 Uses and Limitations

Medicare data has been used to evaluate enrollment, spending, and healthcare delivery. It has also been used to estimate survival and prevalence. In analyzing Medicare data it is important to understand Medicare coverage (e.g. when deductibles are triggered, maximum days allowed) and limitations. Medicare data do not include data for Health Maintenance Organization (HMO) enrollees, care provided at certain settings, and selected services.[81] These include care provided at VA hospitals or clinics; some cases where Medicare is the secondary payer; coverage provided by Medigap policies; long term care at home or in a nursing home; or routine physicals.

5. Medstat MarketScan®

5.1 Description

The Medstat MarketScan® database is a large proprietary, claims database with patient and encounter data. Detailed enrollment, health resource utilization, and expenditure information are available for beneficiaries across sites and types of providers over time from a selection of large

employers, health plans, and government and public organizations. The database consists of approximately 100 payers and 93 million patients. The MarketScan® population consists of insured employees, early retirees, COBRA continuees, Medicare retirees, and eligible dependents.[82-83]

5.2 Population and Design

The MarketScan® population is: active employees and their dependents; early retirees and their dependents; Consolidated Omnibus Budget Reconciliation Act (COBRA) continuees; and Medicare-eligible active and retirees and their Medicare-eligible dependents with employer-provided Medicare Supplemental plans. The database consists of approximately 93 million patients.[82-83] For this study, a dataset has been created to include all adults undergoing bariatric surgery between 1997 and 2007 and a cohort of obese non-surgical adults enrolled between 2002 and 2007. Bariatric and obese adults as determined by procedure codes (CPT-4 codes, ICD-9-CM procedure codes) and diagnosis codes (ICD-9-CM Diagnosis Codes) respectively.

5.3 Data Elements

The Commercial Claims and Encounters and Medicare Supplemental and Coordination of Benefits (COB) data for years 2002-2007 will be used for this study. The Commercial and Claims and Encounters database consists of medical and surgical claims data for: active employee, early retirees, COBRA continuees, and eligible dependents insured by employer-sponsored plans. The Medicare Supplemental and COB database consists of medical and surgical claims data for Medicare-eligible active and retired employees and their Medicare-eligible dependents with employer-sponsored Medicare Supplemental plans. Data for the Medicare Supplemental and COB database are only included for plans where the paid amount is available for both Medicare and employee.[83]

Included data in this source are:

- Medical / surgical;
  - Inpatient Admissions
  - Inpatient Services
  - Outpatient Services
  - Facility Header
  - Outpatient Pharmaceutical Claims
- Population – Demographic information;
- Annual Enrollment Summary; and
- Enrollment Detail.

The Inpatient Admission data set contains a summary of the encounters or claims associated with a hospital admission. It includes the principal procedure, additional procedures (up to 14 in chronological order), principal diagnosis, additional diagnoses (up to 14 in chronological order), Major Diagnostic Category (MDC), and Diagnosis Related Group (DRG). MDCs and DRGs were determined by DRG Grouper Version 19.0.[84] A room and board claim must be present to be included in the Inpatient Admission data. The Inpatient Services data contains the individual facility and encounters and services.[83] The Outpatient Services data set consists of physician office, hospital outpatient facility, emergency room, and outpatient facility visits. Some claims

may also be present in the Inpatient Services data because the claim was not incorporated into an inpatient admission (e.g. no room and board charges). The Populations data set contains quarterly counts of all covered persons for Medical/Surgical and Outpatient Pharmaceutical claims regardless of whether claims have been submitted. These counts reflect a specific point in time; typically the midpoint of a quarter. The Outpatient Pharmaceutical data are available for many individuals represented in the medical/surgical and populations data. The Enrollment tables contain demographics, plan, and continuous enrollment information for users and non-users of health services. And, the Red Book data set contains price information provided by manufacturers.

5.4 Uses and Limitations

Health resource utilization, expenditures, and enrollment are included in the MarketScan® data. The data can be used for health economics and health outcomes research. For example, indirect costs and burden of illness can be assessed. Validations are conducted to ensure that the claims and enrollment data are complete, accurate and reliable.[82-83]

While this data provides expenditures, the limitations of partial and fully capitated plans should be considered. Managed care services are often pre-paid in fixed amounts. For this reason less financial information is collected at service. Some managed care plans produce an encounter record instead of a claim for reimbursement. An encounter record contains demographic information, provider characteristics, and diagnosis and procedure codes. In general, encounter data contain limited financial information. Payment amounts may amount to $1 or $0 and do not include monthly or other fees. Some managed care plans are starting to improve encounter data with fee-for-service equivalent amounts. Fee-for-service equivalents are intended to approximate customary charges for medical service, however, these are still in the early stages of development. Copayments, deductibles, and COBs are considered reliable. Fee-for-service equivalents can be explored by examining records where copayments (COPAY) and payment (PAY) are greater than $0. Encounter data have been tested against plan-by-plan utilization rates. Plans that appear to submit incomplete data were excluded from the database.[82]

6. National Center for Health Statistics - National Health and Nutrition Examination Survey

6.1 Description

The National Health and Nutrition Examination Survey (NHANES) is a nationally representative survey of health and nutrition among adults and children in the U.S. conducted by the NCHS and CDC. The survey is unique in that it combines interviews and physical examinations. It started in the 1960s and has been conducted as a series of surveys focusing on different population groups or health topics. In 1999, the survey became a continuous program that has a changing focus on a variety of health and nutrition measurements to meet emerging needs. The data are available for public use.

6.2 Population and Design

The survey examines a nationally representative sample of approximately 5,000 persons each year. These persons are located in counties across the U.S., 15 of which are visited each year. The sample for the survey is selected to represent the U.S. population of all ages. To produce

reliable statistics, NHANES over-samples persons 60 and older, African Americans, and Hispanics.

The NHANES interview includes demographic, socioeconomic, dietary, and health-related questions. The examination component consists of medical, dental, and physiological measurements, as well as laboratory tests administered by highly trained medical personnel. All participants visit the physician. Dietary interviews and body measurements are included for everyone. All but the very young have a blood sample taken. In general, the older the individual, the more extensive the examination.

6.3 Data Elements

The main data elements include:

- Health conditions and diseases (e.g. diabetes, kidney disease)
- Environmental exposures
- Nutrition
- Obesity
- Oral health
- Physical fitness and physical functioning
- Reproductive history and sexual behavior
- Vision and hearing

NHANES 1999-2004 data are in the process of being linked to NDI. The public use NHANES and linked mortality will be available fall 2009. All linked mortality files will have death data available through 2006.[85]

The questionnaires can be found at: http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm

6.4 Uses and Limitations

NHANES is useful for examining weight related health. It has been used to estimate overweight prevalence and track obesity trends. The data can be used to estimate prevalence of major conditions and diseases and related risk factors. It can be used to monitor nutrition, environmental exposures, and infectious disease. Since continuous NHANES is an ongoing program, the data contributes to annual estimates that are comparable year to year. For small populations and less prevalent conditions and disease, tracking over several years is required to obtain adequate estimates.

The NHANES data will be useful to this study as it can provide nationally representative estimates of obesity and major diseases. The NHANES is a good source for BMI as the data are based on standardized measurements of weight and height. For this study, the data will be used to estimate trends for the prevalence of obesity and the prevalence of selected diseases/conditions and mortality for obese cohorts.

7. National Center for Health Statistics - National Health Interview Survey

7.1 Description

The National Health Interview Survey (NHIS) is a nationally representative survey of health in the civilian, non-institutionalized population of the U.S. It is a principal source of information on

the health and is one of the major data collection programs of the NCHS which is part of the CDC. The National Health Survey Act of 1956 provided for a continuing survey and special studies to secure accurate and current statistical information on the amount, distribution, and effects of illness and disability in the U.S. and the services rendered for or because of such conditions. The survey referred to in the Act, now called the National Health Interview Survey, was initiated in July 1957. Since 1960, the survey has been conducted by NCHS, which was formed when the National Health Survey and the National Vital Statistics Division were combined. The data are available for public use.

7.2 Population and Design

While the NHIS has been conducted continuously since 1957, the content of the survey has been updated about every 10-15 years. In 1996, a substantially revised NHIS questionnaire began field testing. The NHIS covers the civilian non-institutionalized population residing in the United States at the time of the interview. Because of technical and logistical problems, several segments of the population are not included in the sample or in the estimates from the survey. Examples of persons excluded are patients in long-term care facilities; persons on active duty with the Armed Forces (though their dependents are included); persons incarcerated in the prison system; and U.S. nationals living in foreign countries.

The National Health Interview Survey is a cross-sectional household interview survey. Sampling and interviewing are continuous throughout each year. The sampling plan follows a multistage area probability design that permits the representative sampling of households and non-institutional group quarters (e.g., college dormitories). The sampling plan is redesigned after every decennial census. The current sampling plan was implemented in 2006. It has many similarities to the previous sampling plan, which was in place from 1995 to 2005. The first stage of the current sampling plan consists of a sample of 428 PSU's drawn from approximately 1,900 geographically defined PSU's that cover the 50 States and the District of Columbia. A PSU consists of a county, a small group of contiguous counties, or a metropolitan statistical area. Approximately 40,000 households participate each year.

The NHIS questionnaire that was used from 1982-1996 consisted of two parts: (1) a set of basic health and demographic items (known as the Core questionnaire), and (2) one or more sets of questions on current health topics. The Core questionnaire remained the same over that time period while the current health topics changed depending on data needs. The Core questionnaire, while collecting useful data on health conditions and utilization, did not collect any information on insurance, access to health care, or health behaviors. In addition, much of the interview time in the Core questionnaire was devoted to collecting detailed information on events such as doctor visits and hospitalizations rather than on information that would better characterize the individual. The 1997 revision of the NHIS questionnaire has attempted to address these and other shortcomings.

The revised NHIS questionnaire, implemented since 1997, has Core questions and Supplements. The Core questions remain largely unchanged from year to year and allow for trends analysis and for data from more than one year to be pooled to increase sample size for analytic purposes. The Core contains four major components: Household, Family, Sample Adult, and Sample Child.

7.3 Data Elements

The mail data elements include:

- Patient characteristics;
- Clinical conditions;
- Inpatient and outpatient healthcare utilization

NHIS 1986-2004 (and possible 2005) data are in the process of being linked to NDI. The public use NHIS and linked mortality will be available fall 2009. All linked mortality files will have death data available through 2006.[85] Survey forms can be found at: http://www.cdc.gov/nchs/nhis/quest_doc.htm

7.4 Uses and Limitations

NHIS data are used widely throughout the DHHS to monitor trends in illness and disability and to track progress toward achieving national health objectives. The data are also used by the public health research community for epidemiologic and policy analysis of such timely issues as characterizing those with various health problems, determining barriers to accessing and using appropriate health care, and evaluating Federal health programs. The NHIS data may be used to estimate resource use by BMI. However, the NHIS is the sampling frame for MEPS. Currently, there are no plans to link the NHIS and MEPS data for this study. The NHIS data will provide an additional year (2007) not available in MEPS to date. The overlap of the two data sources will be given special consideration in future analyses.

Table 9: Data elements

DATA ELEMENTS	LITERATURE REVIEW	AF	GHC	LABS	MEDICARE	MEPS	MEDSTAT	NCHS NHANES	NCHS NHIS
DEMOGRAPHIC	X	X	X	X	X	X	X	X	X
CLINICAL CHARACTERISTICS	X	X	X	X	X		X	X	
BMI	X	X	X	X		X		X	X
Longitudinal or cross-sectional	L, C	L	L	L	L	L, C	L	C	C
DISEASES/CONDITIONS	X	X	X	X	X	X	X	X	X
Medical Interventions	X	X	X	X	X		X		X
Surgical Interventions	X	X	X	X	X		X		
Gastric Bypass	X	X	X	X	X		X		
Adjustable Gastric Banding	X	X	X	X	X		X		
Complications/Interventions		X	X	X	X		X		
HEALTHCARE RESOURCE USE		X	X	X	X	X	X		X
Outpatient		X	X	X	X	X	X		X
Inpatient		X	X	X	X	X	X		X
Drug, device, diagnostic		X	X	X		X	X		
HEALTHCARE COSTS	X	X	X		X	X	X		
QUALITY OF LIFE	X			X		X			
MORTALITY	X	X	X	X	X	X	X	X	X

X = Data available
C = Cross-sectional
L = Longitudinal

Source: BOOM Research

Table 10: Data overlap

DATA OVERLAP	AF	GHC	LABS	MEDICARE	MEPS	MEDSTAT	NCHS NHANES	NCHS NHIS
Cohort Years (if different)						1997-2007		
Data Years	2001-2007	1990-2008	2005-2008	2004-2008	1997-2006	2002-2007	1999-2006	1997-2007
Population	AF beneficiaries - TRICARE HC delivery system	WA beneficiaries of GHC HC delivery system	Bariatric pts at consortium centers in NC, ND, NY, OR, PA, WA	US Medicare bariatric pts 65+	US sample of civilian non-inst	US sample of commercially insured from large employers and gov; Medicare sample	US sample	US sample of civilian non-inst
AF		X	x				X	X
GHC					X		X	X
LABS				X	X	X	X	X
MEDICARE					X	X	X	X
MEPS						X	X	X
MEDSTAT							X	X
NCHS NHANES								X
NHANES NHIS								

X = potential overlap

*** potential overlap with SCOAP but not CHARS**

Source: BOOM Research

Table 10A: Overlap identifiers

OVERLAP IDENTIFIERS	AF	GHC	MEDICARE	MEPS	MEDSTAT	NCHS NHANES	NCHS NHIS
Cohort Years (if different)					1997-2001		
Data Years	2001-2007	1990-2008	2004-2008	1997-2006	2002-2007	1999-2006	1997-2007
Population	AF beneficiaries - TRICARE HC delivery system	WA beneficiaries of GHC HC delivery system	US Medicare bariatric pts 65+	US sample of civilian non-inst	US sample of commercially insured from large employers and gov; Medicare sample	US sample	US sample of civilian non-inst
Identifiers							
Medicare ID			*				
DOB or Age	X	X	X	X	X	X	X
Sex	X	X	X	X	X	X	X
Race	X	X	X	X	X	X	X
Zip	X	X	X		X	*	*
City							
State			X				
Date of surgery/visit	X	X	X		X		
Insurance	X	X	X	X	X		
Veteran/AD status	X						

*** collected but not available in PUF**

Source: BOOM Research

Appendix 3
Descriptive Outcomes: The burden of surgical costs/expenses and outcomes

Table 11. Medicare beneficiary patient characteristics by procedure type and overall, 2004-2008

Patient characteristics	Open bypass (N = 12,702)		Lap bypass (N= 20,842)		Lap band (N= 11,272)		Biliopancreatic diversion (N= 376)		Sleeve (N= 1,117)		Overall (N=46,309)	
	n	%	n	%	n	%	n	%	n	%	n	%
Age at bariatric surgery												
18-<25	81	0.64	127	0.61	41	0.36	1	0.27	10	0.90	260	0.56
25-<35	1,088	8.57	1,542	7.40	432	3.83	38	10.11	62	5.55	3,162	6.83
35-<45	2,610	20.56	3,960	19.00	1,281	11.37	56	14.89	176	15.76	8,083	17.46
45-<55	4,011	31.59	5,905	28.34	2,125	18.85	106	28.19	256	22.92	12,403	26.79
55-<65	3,259	25.67	5,534	26.56	2,933	26.02	99	26.33	288	25.78	12,113	26.16
65+	1,647	12.97	3,770	18.09	4,459	39.56	76	20.21	325	29.10	10,277	22.20
Female	9,481	74.71	16,029	76.94	8,248	73.18	248	65.96	817	73.14	34,823	75.23
Race												
White	10,214	80.45	16,712	80.20	9,364	83.08	324	86.17	884	79.14	37,498	80.99
Black	1,980	15.60	3,127	15.01	1,518	13.47	25	6.65	180	16.11	6,830	14.75
Hispanic	220	1.73	352	1.69	178	1.58	13	3.46	22	1.97	785	1.70
Other	249	1.96	510	2.45	155	1.38	13	3.46	27	2.42	954	2.06
Unknown	33	0.26	137	0.66	56	0.50	1	0.27	4	0.36	231	0.50
Year of bariatric surgery												
2004	5,367	42.25	295	1.42	0	0	0	0	353	31.60	6,015	12.99
2005	3,440	27.08	5,093	24.44	2	0.02	54	14.36	490	43.87	9,079	19.61
2006	1,553	12.23	4,004	19.21	1,887	16.74	61	16.22	104	9.31	7,609	16.43
2007	1,294	10.19	5,180	24.85	3,822	33.91	97	25.80	73	6.54	10,466	22.60
2008	1,048	8.25	6,270	30.08	5,561	49.33	164	43.62	97	8.68	13,140	28.37

Table 12. Medicare beneficiary mortality by bariatric surgery type and complications, 2004-2008

	All cause mortality within 30 days		Bariatric PLOS or re-hospitalization within 30 days		No complications within 30 days	
	n	%	n	%	n	%
Open bypass (N= 12,702)	158	1.24	3,463	27.26	9,081	71.49
Day 31 – 1 year			3,463		9,081	
Death			147	4.24	101	1.11
1 year – 2 year			3,109		8,404	
Death			59	1.90	85	1.01
2 year – 3 year			2,759		7,502	
Death			40	1.45	74	0.99
3 year – 4 year			2,385		6,473	
Death			50	2.10	62	0.96
Lap bypass, (N= 20,842)	123	0.59	3,212	15.41	17,507	84.00
Day 31 – 1 year			3,212		17,507	
Death			112	3.49	138	0.79
1 year – 2 year			2,433		13,254	
Death			36	1.48	92	0.69
2 year – 3 year			1,618		8,741	
Death			22	1.36	68	0.78
3 year – 4 year			987		5,196	
Death			8	0.81	36	0.69
Lap band (N= 11,272)	26	0.23	737	6.54	10,509	93.23
Day 31 – 1 year			737		10,509	
Death			12	1.63	43	0.41
1 year – 2 year			465		6,350	
Death			8	1.72	33	0.52
2 year – 3 year			187		2,458	
Death			0	0.00	11	0.45
3 year – 4 year			28		332	
Death			1	3.57	0	0.00
Biliopancreatic diversion (N= 376)	4	1.06	122	32.45	250	66.49
Day 31 – 1 year			122		250	
Death			6	4.92	8	3.20
1 year – 2 year			77		159	
Death			3	3.90	1	0.63
2 year – 3 year			46		81	
Death			1	2.17	0	0.00
3 year – 4 year			20		36	
Death			0	0.00	1	2.78
Sleeve (N= 1,117)	6	0.54	137	12.26	974	87.20
Day 31 – 1 year			137		974	
Death			9	6.57	7	0.72
1 year – 2 year			114		901	
Death			2	1.75	8	0.89
2 year – 3 year			91		846	
Death			2	2.20	11	1.30
3 year – 4 year			80		783	
Death			3	3.75	9	1.15

NOTES: (1) shaded cells indicate not applicable; (2) PLOS = prolonged length of stay and is defined as a hospital stay greater than 5 days for bariatric admission; (3) no complications is defined as survived beyond 30 days from bariatric surgery, no PLOS, and no hospital readmission within 30 days of bariatric surgery; (4) the amount of possible mortality follow-up will vary by bariatric surgery date and this is reflected in the table; (5) column percents will not sum to 100; and (6) the percents in the first row for each procedure are row percents and will sum to 100.

Table 13. Medicare beneficiary average costs by bariatric surgery type and complications, 2004-2008

	All cause mortality within 30 days		Bariatric PLOS or re-hospitalization within 30 days		No complications within 30 days	
	N	Mean $	N	Mean $	N	Mean $
Open bypass						
0 – 30 days	158	33,476	3,463	33,804	9,081	16,810
Day 31 – 1 year			3,452	25,239	9,033	10,740
1 year – 2 year			3,052	19,512	8,222	12,128
2 year – 3 year			2,669	16,801	7,238	11,197
3 year – 4 year			2,245	15,062	6,072	9,666
Lap bypass						
0 – 30 days	123	34,713	3,212	32,840	17,507	15,689
Day 31 – 1 year			3,167	22,137	17,013	9,294
1 year – 2 year			2,216	14,609	12,068	9,976
2 year – 3 year			1,417	12,774	7,690	8,874
3 year – 4 year			833	8,245	4,338	5,630
Lap band						
0 – 30 days	26	16,861	737	25,901	10,509	12,877
Day 31 – 1 year			726	15,715	9,984	7,505
1 year – 2 year			390	12,021	5,272	8,228
2 year – 3 year			123	6,739	1,732	6,011
3 year – 4 year					2	6,478
Biliopancreatic diversion						
0 – 30 days	4	48,011	122	30,825	250	19,662
Day 31 – 1 year			115	20,584	236	9,102
1 year – 2 year			69	14,459	130	12,280
2 year – 3 year			37	9,912	68	9,128
3 year – 4 year			17	3,741	32	10,421
Sleeve						
0 – 30 days	6	14,505	137	38,695	974	16,810
Day 31 – 1 year			135	28,972	970	11,315
1 year – 2 year			111	26,883	893	13,790
2 year – 3 year			90	24,139	835	13,631
3 year – 4 year			73	18,958	736	9,275

NOTES: (1) shaded cells indicate not applicable; (2) PLOS = prolonged length of stay and is defined as a hospital stay greater than 5 days for bariatric admission; (3) no complications is defined as survived beyond 30 days from bariatric surgery, no PLOS, and no hospital readmission within 30 days of bariatric surgery; (4) the amount of possible follow-up will vary by bariatric surgery date and this is reflected in the table; and (5) costs are defined as the sum of amounts paid by Medicare, the beneficiary, and other primary payers for inpatient, outpatient, and durable medical equipment in 2009 dollars.

Table 14. Medstat beneficiary patient characteristics by procedure type and overall, 2002-2007

Patient characteristics	Open bypass (N = 26,606)		Lap bypass (N= 29,635)		Lap band (N= 4,433)		Biliopancreatic diversion (N= 150)		Sleeve (N= 618)		Overall (N= 61,442)	
	n	%	n	%	n	%	n	%	n	%	n	%
Age at bariatric surgery												
18-<25	899	3.38	1,020	3.44	147	3.32	2	1.33	23	3.72	2,091	3.40
25-<35	4,804	18.06	5,722	19.31	713	16.08	13	8.67	101	16.34	11,353	18.48
35-<45	7,600	28.56	8,846	29.85	1,253	28.27	46	30.67	157	25.40	17,902	29.14
45-<55	8,723	32.79	9,170	30.94	1,370	30.90	49	32.67	209	33.82	19,521	31.77
55-<65	4,579	17.21	4,877	16.46	950	21.43	40	26.67	128	20.71	10,574	17.21
65+	1	0.00	0	0	0	0	0	0	0	0	1	0.00
Female	21,585	81.13	24,273	81.91	3,596	81.12	117	78.00	491	79.45	50,062	81.48
Region												
Northeast	1,978	7.43	1,859	6.27	453	10.22	7	4.67	215	34.79	4,512	7.34
North Central	7,687	28.89	7,028	23.72	1,248	28.15	60	40.00	111	17.96	16,134	26.26
South	10,343	38.87	12,804	43.21	2,146	48.41	46	30.67	196	31.72	25,535	41.56
West	6,384	23.99	7,778	26.25	568	12.81	37	24.67	94	15.21	14,861	24.19
Unknown	214	0.80	166	0.56	18	0.41	0	0	2	0.32	400	0.65
Year of bariatric surgery												
2002	4,396	16.52	352	1.19	0	0	1	0.67	39	6.31	4,788	7.79
2003	7,090	26.65	2,141	7.22	0	0	1	0.67	96	15.53	9,328	15.18
2004	8,799	33.07	4,370	14.75	37	0.83	0	0	129	20.87	13,335	21.70
2005	3,459	13.00	8,365	28.23	257	5.80	61	40.67	182	29.45	12,324	20.06
2006	1,716	6.45	7,292	24.61	1,559	35.17	41	27.33	79	12.78	10,687	17.39
2007	1,146	4.31	7,115	24.01	2,580	58.20	46	30.67	93	15.05	10,980	17.87

Table 15. Medstat beneficiary average inpatient costs by bariatric surgery type and re-hospitalization, 2002-2007

	Death at bariatric discharge		Re-hospitalization within 30 days		No early complications	
	N	Mean $	N	Mean $	N	Mean $
Open bypass						
0 – 30 days	155	93,014	1,737	50,136	22,676	24,507
Day 31 – 1 year			1,318	10,852	17,416	2,939
1 year – 2 year			931	7,210	12,396	3,705
2 year – 3 year			657	4,861	8,897	3,385
3 year – 4 year			336	4,744	4,463	2,967
Lap bypass						
0 – 30 days	51	142,405	1,639	43,915	25,631	24,332
Day 31 – 1 year			966	8,198	15,090	2,624
1 year – 2 year			503	4,711	7,686	3,143
2 year – 3 year			187	7,448	2,790	2,730
3 year – 4 year			53	7,007	799	2,328
Lap band						
0 – 30 days	4	58,590	100	32,051	3,912	18,614
Day 31 – 1 year			42	4,363	1,297	1,743
1 year – 2 year			5	0	173	3,537
2 year – 3 year					21	8,464
3 year – 4 year						
Biliopancreatic diversion						
0 – 30 days	1	219,259	14	94,632	131	31,535
Day 31 – 1 year			6	2,696	73	1,281
1 year – 2 year			4	16,949	33	4,908
2 year – 3 year					1	0
3 year – 4 year					1	20,222
Sleeve						
0 – 30 days	1	40,807	26	60,024	553	23,145
Day 31 – 1 year			14	11,546	372	3,347
1 year – 2 year			9	882	238	4,065
2 year – 3 year			6	3,060	110	2,892
3 year – 4 year			4	3,748	39	1,401

NOTES: (1) shaded cells indicate not applicable; (2) no early complication is defined as alive at bariatric discharge and no re-hospitalization within 30 days; (3) the amount of possible follow-up will vary by enrollment and this is reflected in the table; and; (4) costs are defined as the total gross payments to all providers who submitted claims for covered services rendered during all inpatient admissions in 2009 dollars.

Appendix 4
Budget Impact Analysis of Bariatric Surgery for Morbid Obesity Abstract

Obesity is reported to increase mortality, morbidity, and costs. Bariatric surgery remains the most effective treatment for long-term weight loss. We developed a payer-based Budget Impact Model (BIM) to assess “Return On Investment (ROI)” for bariatric surgery in obesity compared to non-operative interventions.

The purpose of this BIM is to estimate the financial consequences of adoption of different types of Bariatric surgeries within a specific health care setting given inevitable resource constraints. The BIM can be customized based on the characteristics of the population of interest (i.e. number of lives covered, age, gender, and body mass index) and the alternatives of interventions presented (i.e. Different types of bariatric surgeries and/or different degrees of use of each procedure). Since each bariatric procedure has different costs, and may be associated with different levels of weight loss and complications; the inputs used for the costs, complications, and mortality rates, are derived from a Cost-Effectiveness Model from nationally representative databases and the best estimates from the published literature.

Average annual costs per patients for each procedure are multiplied by the number of eligible subjects receiving the specific procedure. These costs are accumulated over a 10-year period and compared to the cumulative costs of eligible subjects for bariatric surgery who did not receive the procedure. Results are expressed as the increment of total costs per member per year. By examining different scenarios, with different levels of eligibility and mix of surgical procedures, decision makers could estimate accurately the ROI associated with each alternative over time.

<u>Appendix 5</u>
Award Beneficiaries
The following individuals received payment from this award:

From Ventura Healthcare Systems, LLC:
Larry Belenke and Franklin D. Carr

From University of Washington:
David R. Flum, MD, MPH, Sean D. Sullivan, PhD, Louis P. Garrison, PhD, Andrew Wright MD, MS, Rafael Alfonso, MD, MSc, Bruce Wang PhD, Edwin Wong PhD , Allison Devlin Rhodes MS, Katrina Golub, MPH, Hao He, PhD, Andy Louie, Erin Machinchick, Brad Kramer and Kara MacLeod MPH

From Group Health Cooperative, Center for Health Studies:
David Arterburn, MD, MPH, Malia Olivier and Rene Hawkes

Independent Consultants:
Louis Martin, MD, MS (Samaritan Physicians) and Ava Coe (Contract Employee)